

ViewECG

Medical Device System Doctor's User Manual



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READ THIS FIRST

First, read the safety measures in Section 1.



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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

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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
	Medical Device
	Consult Instructions for Use
	European Conformity

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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.

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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

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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

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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,

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- 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](#).

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1.5. Troubleshooting

Table 4 presents the potential problems and corresponding solutions.

Table 4: Problems and solutions.

Problem	Solution
<i>I forgot my password and I am unable to reset it</i>	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.
<i>No graphics represent the ECG signal</i>	Check if you use the latest browser capable of displaying SVG graphics.

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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,

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- 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.

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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

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- 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 disorders¹. 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 hospitalizations². Considering this, all recent Guidelines for managing Syncope, Atrial fibrillation, Ventricular arrhythmia, and prevention of Sudden Cardiac Death³ 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.

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.

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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 is one month⁴. Clinical decision support systems are intelligent systems that digitize and provide evidence-based guidelines, clinical pathways, and algorithms, facilitating personalized, timely, and evidence-based treatment⁵.

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.

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 J*2020; doi:10.1093/eurheartj/ehaa612

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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.

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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

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

Published on 31.07.2023

Device labelling

CE 1304

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

UDI-DI: 383008599000128



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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.

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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.

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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 specification⁶ of annotations and episodes.

⁶ PhysioBank Annotations - <https://www.physionet.org/physiobank/annotations.shtml>.

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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 Doctor

The doctor's home page appears when a doctor logs in to the web application with valid credentials.

4.1. Doctor's Home Page

The doctor's home page displays the "My patients" page and features four menu options: "Upload files," "Create patient," "Completed reports," and "Draft reports." The "My patients" page also displays the doctor's list of patients (Figure 2).

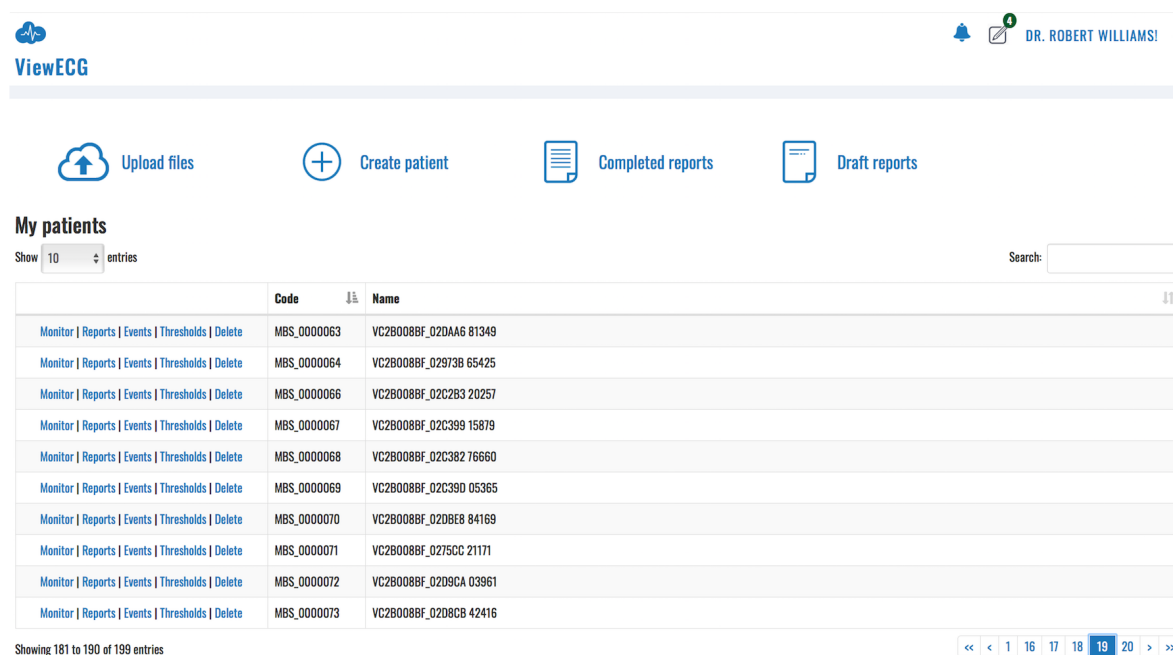


Figure 2: Doctor's home page is, by default, a list of patients.

My Patients' Page Header

The header row contains the ViewECG logo in the top left corner. The ViewECG logo is present on every page of the web application. A click on the logo always displays the home page, "My patients."

The right side of the header contains the "Notification icon," a link to "Draft reports," the Doctor's name, and a "Settings icon."

A click on the "Notification icon" opens a notifications page on the right side of the browser's window. This page contains a list of system notifications, such as those generated when the uploaded files are processed and ready to be monitored.

If any started reports have not been completed, a link to "Draft reports" will appear next to the "Alarm icon." Clicking this icon will redirect the user to a page featuring a list of draft reports with options for further handling.

The "Doctor's name" is linked to the account details page.

A click on the "Settings icon" displays a drop-down-like menu with two listed links: a link to the doctor's profile details page and a link for logging off. If the user is currently visiting the monitoring page, the "Settings menu" offers additional preference toggles, described in detail in the monitoring section of this manual.

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List of Patients

My patients' list (Figure 2) presents only the last ten patients as a default option.

The user can adjust the preferred number of patients displayed in the list by clicking on the drop-down menu next to the "Show entries" message (Figure 3) below the heading "My patients."

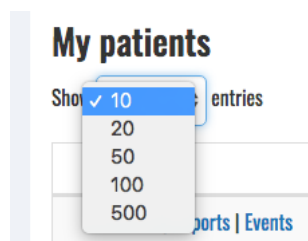


Figure 3: Selecting the number of entries displayed in the list.

A "Search option" is available on the right above the table that displays the list. You can enter a part of the patient's name or code, and the list will be filtered to show only those patients whose name or code contains the text entered in the search box.

The list is presented in table format. Each row contains a cell with three links, a cell with the patient's code, and a cell with the patient's name. By default, the list is sorted so that the last entered patient is enlisted on top. You can change the sorting by clicking on the "Code" or "Name" column heading to change the ordering of the displayed items.

The list of patients shows three links preceding the code and name cells for each displayed patient. These links are to pages for each specific patient: "Monitoring," "Reports," and "Events." Each of these features will be described in its corresponding section.



Figure 4: List of navigation buttons.

The next page with a selected number of patients can be displayed by clicking the consecutive page number or a navigation button. The displayed navigation buttons (Figure 4) can be:

- Two left arrows ("<<") – display the leftmost page (go to the beginning),
- One left arrow ("<") – displays the previous page,
- One right arrow (">") – displays the next page, and
- Two right arrows (">>") – display the rightmost page (go to the end).

An information line at the bottom left corner shows the total number of patients and how many are currently displayed in the list.

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System Notifications

The “Notification icon,” resembling a bell, is the leftmost icon of the header’s top right corner (Figure 5).

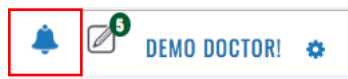


Figure 5: Alarm icon.

It is a link to the “System notifications.” If there are pending system notifications, a notification number is shown at the top right corner of the icon. If there are no new system notifications, no notification count is present. A click on the “Notification icon” will open a notification content tab listing all the notifications that were sent for the user within the current session. The unread notifications are displayed at the top of the notification list and are visually distinctive.

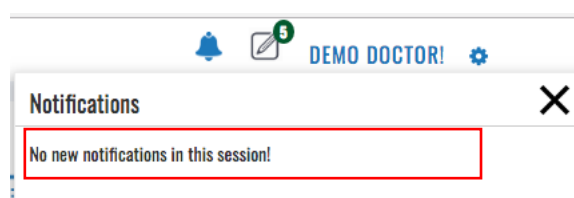


Figure 6: No new system notification.

A “System notification” may include a message that there are "no new notifications in the session" (Figure 6), the “ECG file is successfully uploaded” and the corresponding processing has started, or “Processing finished successfully” (Figure 7), so the user can monitor the uploaded ECG file.

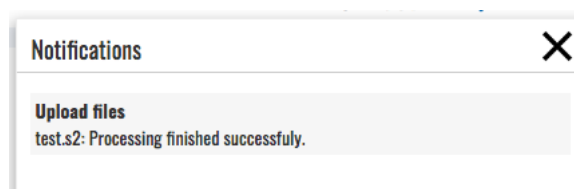


Figure 7: System notification that the processing is finished and ECG is ready for monitoring.

You can close the notification window by clicking the “close” (X) button at the top right corner or by clicking the “Bell icon” again.

Draft Reports

The “Draft reports” icon is next to the alarm icon in the header’s top right corner (Figure 8). The number in the top right corner of the draft report icon shows how many reports have not been completed, for example, five draft reports. The “Draft reports” icon will not be displayed if there are no draft reports.



Figure 8: Draft reports' icon.

A click on the “Draft report’s icon” will display a list of draft reports (Figure 9) that have been started and are not completed. You can access and overview the list of draft reports by standard interfaces whose behavior is the same as that of the interfaces described in the “My patients” section. Additional functionality for this page is the possibility to delete one or multiple draft reports.

DRAFT REPORTS			
Show	10	entries	Search: <input type="text"/>
<input type="checkbox"/>	Created on	Patient	
<input type="checkbox"/>	04.02.2022 11:40:09	VC2B008BF_02DBEE 62686 (MBS_0000084)	
<input type="checkbox"/>	25.01.2022 14:54:13	VC2B008BF_02C399 15879 (MBS_0000067)	
<input type="checkbox"/>	10.12.2021 16:07:46	VC2B008BF_02C2B5 82037 (MBS_0000077)	
<input type="checkbox"/>	12.11.2021 10:27:39	VC2B008BF_01EEC2 08499 (MBS_0000078)	

Showing 1 to 4 of 4 entries

Figure 9: List of draft reports.

Each row in the table contains a selection column, the date and time of the report’s creation, and the patient’s name, followed by a delete report icon. A selection column enables you to select several items for deletion, while a click on a trash icon will delete only the draft report for the selected person.

Delete draft reports
☐

1 reports selected.

Are you sure that you want to delete selected reports?

Delete
Cancel

Figure 10: Confirmation of draft report deletion.

A click on a row of the table enlisting the reports redirects the user to the page for report creation so that the user can continue to complete the report. The reporting tools are explained in the corresponding Reporting section.

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Settings

A click on the “Settings icon” at the top right corner will activate the corresponding drop-down menu (Figure 11). The menu consists of a link to the “Profile” page and a “Log off” link.

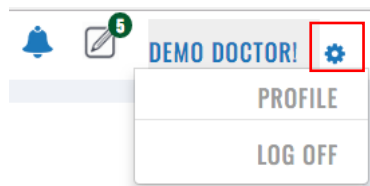


Figure 11: Settings menu options.

You can access the account details page (Figure 12) either by clicking on the “Doctor’s name” in the top right corner of the header or by clicking the “Settings icon” and then selecting the “Profile” option from the drop-down menu.

Change Account Details

Title	<input type="text" value="Dr."/>	User name (Email)	<input type="text" value="doctor@ecgalert.com"/>
First name	<input type="text" value="Demo"/>	Password	Change your password
Last name	<input type="text" value="Doctor"/>	Code	<input type="text"/>
Sex	<input type="radio"/> Male <input checked="" type="radio"/> Female	Language	<input type="text" value="English (United Kingdom)"/>
Date of birth	<input type="text" value="01/01/1995"/>	Picture	 <input type="button" value="Choose file"/> No file chosen
Address	<input type="text" value="Broadway 23/25"/>		<input type="checkbox"/> Remove file
City	<input type="text" value="London"/>		<input type="button" value="Save"/>
Post Code	<input type="text" value="HA0 1AP"/>		
Country	<input type="text" value="United Kingdom"/>		
Phone number	<input type="text"/>		
Work as freelancer	<input type="checkbox"/>		

[Deactivate Account](#)

Figure 12: Profile settings page.

The doctor can change personal data, including title, first and last name, sex, birth date, address, city, postcode, country, phone number, username, password, and language. In addition, the doctor can insert a photo and edit or remove the existing one. Only first and last name, username, and password are obligatory, while the other fields are optional.

You can select an option to work as a freelancer to give an opinion about recorded ECGs for patients.

There are three action buttons. The first one, "Save," will save the changes, "Deactivate user" will deactivate the user, and "Change your password" will allow the user to set up a new password.

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4.2. Most Used Functions

The heading row below the page header on the index page contains shortcuts to the most used functions, including links to “Create a patient,” “Upload ECG files,” “List completed reports,” and “Analysis.”



Figure 13: Most used functions

Upload Files

A click on the menu option “Upload files” will display the Upload files form (Figure 14). You can choose a patient from the drop-down menu or create a new patient by clicking on the corresponding link.

Upload files
Time to upload file depends on the amount and size of the files. Please be patient.

Patient

Files

You can upload more than one file.

Figure 14: Upload files form.

Clicking the active button “Browse” will open a file browser window (Figure 15) for selecting one or several files to be uploaded.

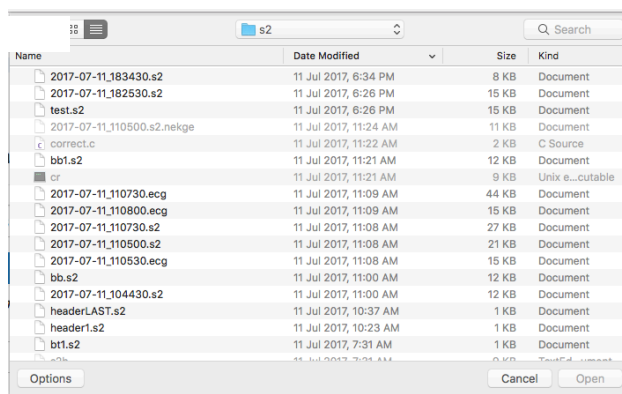


Figure 15: File browsing dialog form to select an ECG or S2 file for upload.

After selecting the files, the upload will start by clicking the “Start transferring” action button. When the upload is complete, a notification count will appear on the “Notification icon.” The user will receive another notification as soon as the file(s) are processed. The notification details can be accessed by clicking the “Notification icon.”

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Create Patient

This page (Figure 16) is accessed upon clicking on the “Create patient” link, which is part of the most used functions sections on the “My patients” page. The user is expected to enter the patient’s name, family name, birth date, gender, weight and height, arrival date, device version being used, e-mail, password, pacemaker use, indications, medications, and affiliation as personal data. Only the name is a mandatory entry. If a patient’s email and password are entered, then the patient can use the patient’s monitoring page.

Create new patient

The form is titled "Create new patient" and is divided into two main sections. The left section contains the following fields: "First name" (text input), "Last name" (text input), "Date of birth" (date picker showing 6/25/1979), "Sex" (radio buttons for Male and Female, with Male selected), "Weight" (text input showing 70), "Height" (text input), "Arrived on" (date picker showing 6/25/2019), and "Device" (dropdown menu showing "Choose..."). The right section contains: "Email" (text input), "Password" (text input), "Confirm password" (text input), "Pacemaker" (checkbox), "Indications" (text input), "Medications" (text input), and "Company" (dropdown menu showing "Test Cardiology"). A "Create" button is located at the bottom left of the form.

[Back to list](#)

Figure 16: Create patient form.

A click on the action button “Create” will create a new record for the patient. Afterward, the doctor can upload recorded ECG files. A click on the link “Back to list” will return to the list of patients or display the previous page.

Completed Reports

The list of completed reports (Figure 17) is accessed by clicking the completed reports link on the “My patients” page.

My Reports

Show entries Search:

Patient	Period	Opinion	Created on
Ronald Washington (A228)	27.10.2017	Underlying rhythm is normal with rates between 54 and 80 BPM. Frequent (20) episodes of ventricular bigeminy detected with a total duration of 11 minutes (19% of total duration) and the longest run of 84 sec. Ventricular beats are multiform.	12.09.2018 12:35:51
Peter Wolf (A230)	27.10.2017	Normal sinus rhythm with rates between 63 and 99 mixed with WPW pre-excitation episodes.	12.09.2018 12:17:52
Samuel Orson (A231)	27.10.2017	Normal sinus rhythm with rates between 49 and 69 BPM and 2:1 block with rates of 34-38 BPM. Abnormal AV conduction with periods of 2:1 AV block and right bundle branch block which appears to be rate-related. A ventricular couplet is identified.	12.09.2018 11:42:30
Carter Ferguson (A233)	27.10.2017	Normal sinus rhythm between 98 and 110 BPM with 704 isolated premature ventricular beats, 60 couplets, and 6 runs of ventricular tachycardia with three beats. Identified 28 episodes of ventricular bigeminy and 1 episode of ventricular trigeminy.	12.09.2018 10:29:08
Tim McCarthy (A105)	27.10.2017	Underlying normal sinus rhythm (heart rate between 72 and 108 BPM. Identified 41 uniform premature ventricular contractions in a measurement of 30 minutes.	02.09.2018 20:12:49
Thomas May (A103)	27.10.2017	Normal sinus rhythm between 64 and 95 BPM. Two isolated supraventricular ectopy beats identified.	02.09.2018 14:07:21
Angus Ray (A102)	27.10.2017	The rhythm is paced with a demand pacemaker. Normal sinus rhythm is between 72-78 BPM. The selected segment shows two paced beats, followed by fusion beats and at the end a normal beat. Four isolated premature ventricular contractions are multiform.	02.09.2018 14:04:21
Orson Porter (A234)	27.10.2017	Normal sinus rhythm between 80 and 95 BPM. Three isolated premature ventricular beats found. Supraventricular tachycardia episode with a run of 50 beats identified with rhythm between 93 and 150 BPM.	02.09.2018 13:49:29
Mark Shield (A101)	27.10.2017	Normal sinus rhythm identified from 51 to 82 BPM. Three isolated supraventricular beats detected.	02.09.2018 12:54:48
John Reynolds (A100)	27.10.2017	Normal sinus rhythm identified with rates between 71 and 92 BPM. 33 isolated supraventricular ectopy beats and one premature ventricular contraction for the recorded period.	02.09.2018 12:45:48

Showing 1 to 10 of 10 entries 1
[Back to list](#)

Figure 17: List of completed reports.

The list is displayed in a table that contains the following columns: patient name, period, opinion, date, and time of creation.

You can access and overview the list of reports using standard navigation interfaces as described in the “My patients” section, including search, selection of multiple items displayed in the list, or selection of the page to be displayed if the list is several pages long.

A click on the link “Back to list” will return to the list of patients or display the previous page.

Reports (Electronic Health Records - EHR)

The reports page for a selected patient can be accessed by clicking on the reports link next to the name on the “My patients” page. It is a subset of the completed reports page since it presents a list of reports filtered to the selected user. All other interfaces resemble it.

Draft Reports

The link leads to the Draft Reports described before.

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4.3. Events

List of Events

The list of events page (Figure 18) is accessible either by clicking the “Events” link next to the patient’s name in the list of patients or by clicking the “Events” link found in the header when visiting the monitoring or report-related pages.

Events for Demo Patient P (A002)

Date [REPORTS](#) [MONITOR](#)

Show entries Search:

Date	Time	Activity	Feeling
20.07.2017	13:45:20		
20.07.2017	13:45:20		
20.07.2017	13:45:20		
20.07.2017	13:45:20		
20.07.2017	13:45:20		
20.07.2017	13:45:20		
20.07.2017	13:45:20		
20.07.2017	13:45:20		
20.07.2017	13:45:20		
20.07.2017	13:45:20		

Showing 11 to 20 of 34 entries << < 1 2 3 4 > >>

[Back](#)

Figure 18: List of events

This is a standard list resembling the one enlisting the patients. The behavior of the interfaces has been previously explained.

The heading displays the patient’s name. The subheading, located below the heading, contains a field for date entry (a click on the empty text box opens a date selection dialog, or the user can enter the date in the field directly). The subheading also contains links to completed reports for the patient and the monitoring section.

The main part of the events page contains a list of all recorded events for the patient, sorted by their time, with the latest listed at the top of the list. Each line displays the date and time and optional activity or feeling if the user entered them while recording the event.

You can change the number of entries shown by clicking on the corresponding drop-down menu next to the “Show entries” label. The search field allows you to enter a specific date or text to search through the feeling and activity fields.

Navigation through the list is possible by clicking a page number or by clicking on navigation buttons for top, previous, next, and last page options that correspond to <<, <, >, and >> icons. An event details page is visited by clicking the appropriate date/time on the displayed list.

Overview of an Event

The “Events details” page overviews a recorded event (Figure 19).

The overview contains a heading with the patient's details (name, date, time, and place of recording, activity, and feeling when the event was recorded), followed by consecutive rows of ECG strips.

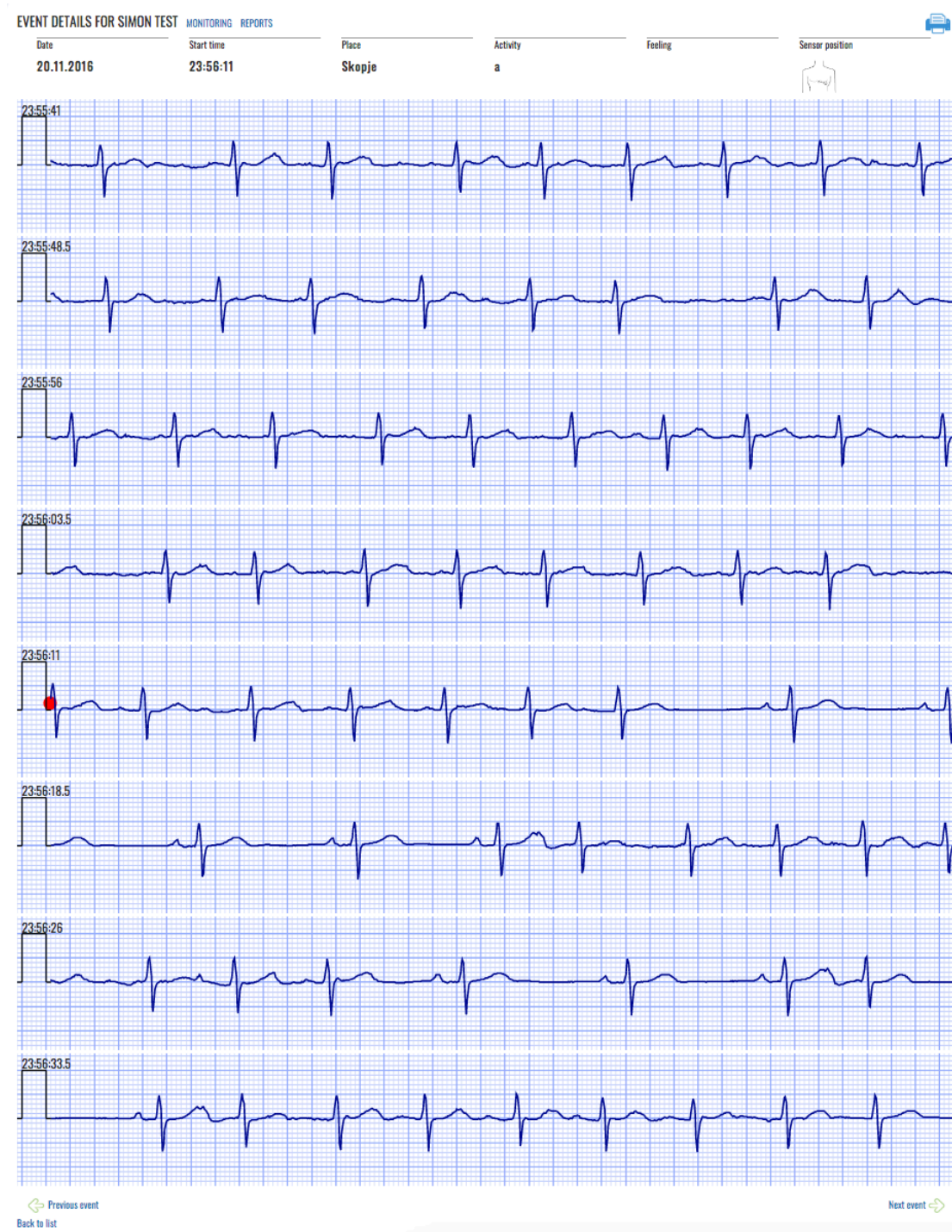


Figure 19: A sample of recorded event.

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Each ECG strip is displayed in a separate row on a grid with standard resolutions of 25mm/cm and 1 mV/cm for more accurate interpretation. Its time duration is 7.5 sec.

According to the event time duration marking, the display may contain eight rows of ECG strips for a 60-second event, 12 for a 90-second event, or 16 for a 120-second event. Furthermore, eight rows fit on one page, and 16 rows fit on two pages.

A red mark is displayed in the middle to represent the exact moment the event was recorded. In the case of a 60-second event, the mark is located at the beginning of the fifth row since the event records 30 seconds prior to event activation and 30 seconds after.

There are two links at the bottom of the page: the leftmost link displays the previous event, and the rightmost link displays the next event (if any).

Printing an Event

The events details page contains a “Printer icon.” Clicking on the icon invokes a dialog form to print the event (Figure 20).

The dialog form depends on the operating system and browser. The user can select the output printer, such as the PDF output, by choosing a folder and entering the filename.

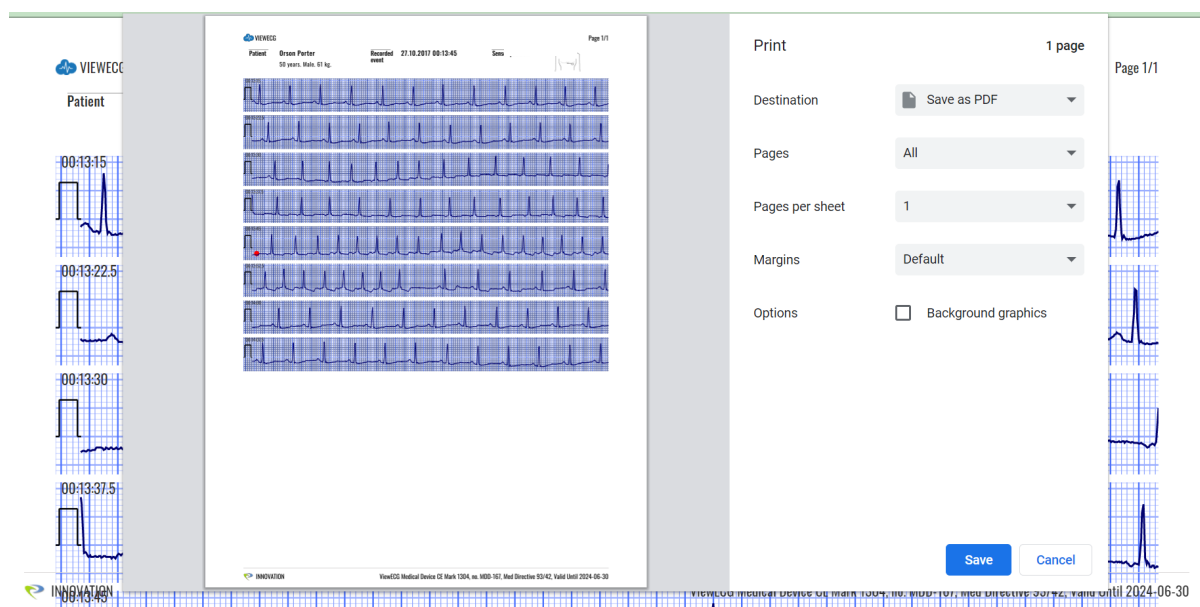


Figure 20: Dialog form to print an event.

The printed page contains personal information relevant to the patient, date, time, and place of the recorded event, activity description during the marked event, and sensor position,

Event in the Monitoring View

An event is marked in the “BPM, Beats, Episodes, and Events navigator” with a yellow triangle figure positioned on the upper side for an event (Figure 21). Hovering over the triangle figure, the info window will show a listing of the exact event occurrence time and activity description.

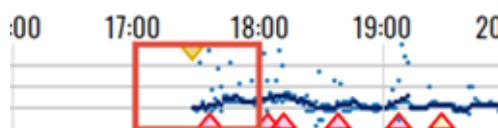


Figure 21: Events in BPM, Beats, or Episodes navigator.

An event is marked in the “List of ECG strips” with a yellow diamond-shaped figure positioned in the ECG strip where the event occurred (Figure 22). Hovering over the figure, the info window will show a listing of the exact event occurrence time and activity description.

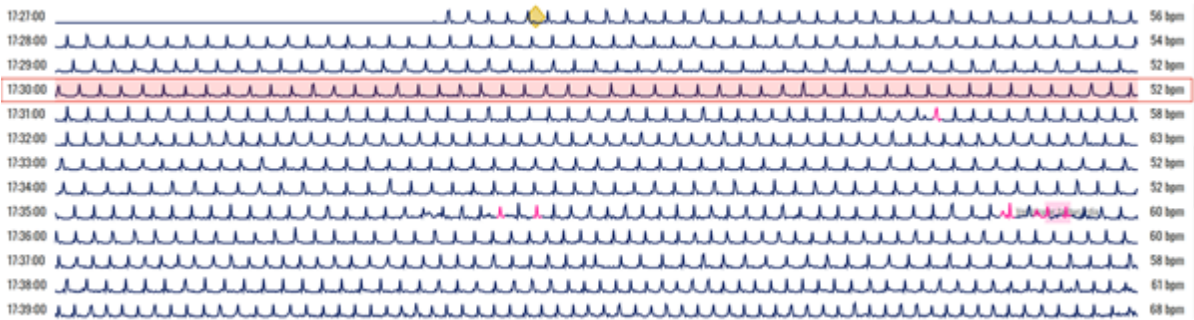


Figure 22: Event in List of ECG strips.

An event is marked in the “Focus chart” with a yellow diamond-shaped figure positioned where the event occurred (Figure 23). Hovering over the figure, the info window will show a listing of the exact event occurrence time and activity description.

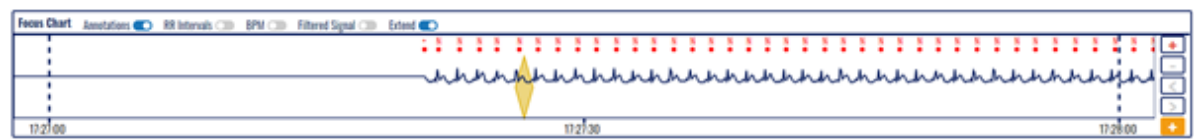


Figure 23: Event in Focus chart.

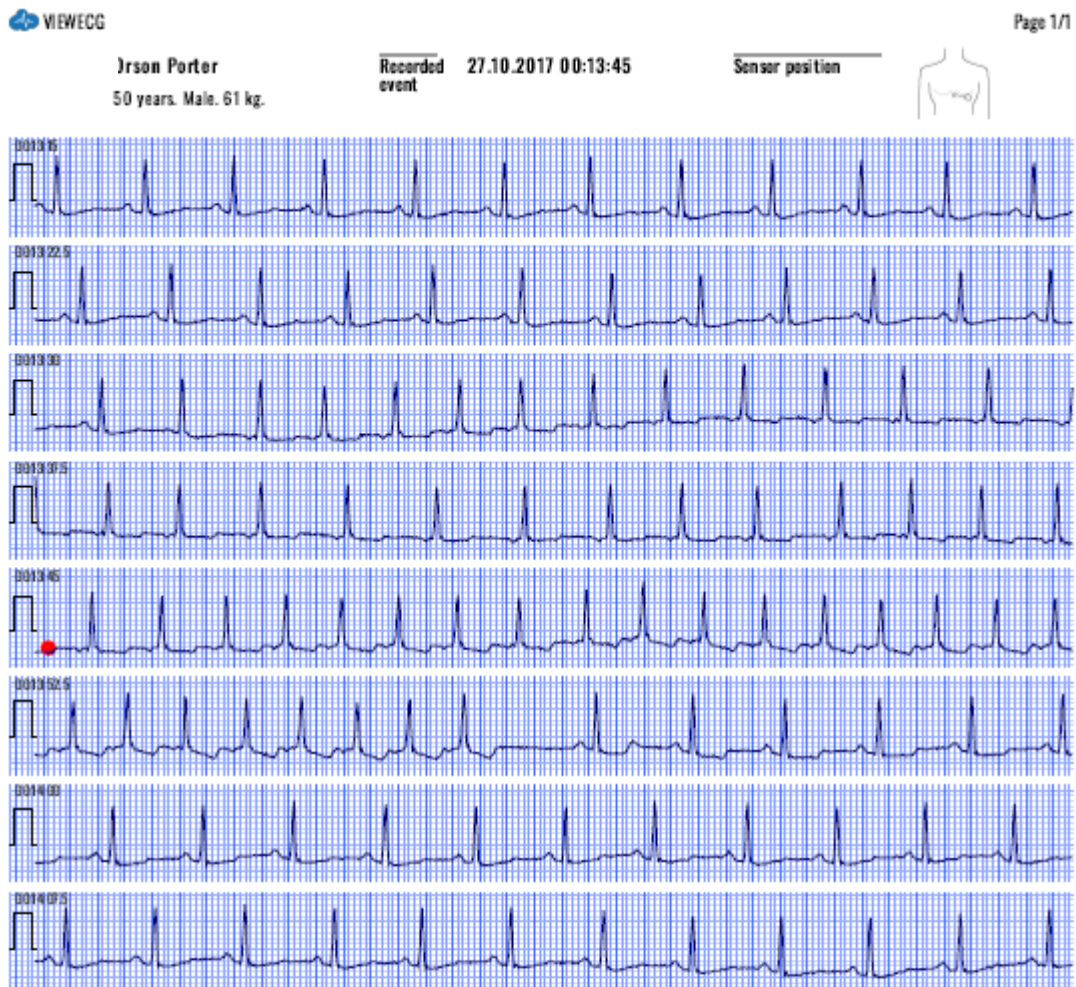


Figure 24: A pdf corresponding to the recorded event.

4.4. Thresholds

A profile with predefined thresholds can be associated with a selected patient. A selected patient can be associated with a set of thresholds by clicking on the “Threshold” next to the patient ID.

Profiles

The profiles page is opened when the profile link is activated, as presented in Figure 25. The list of patient profiles is displayed by their names, followed by a check box to select if it is the default profile, and a list of links to set it as a default profile, to edit, to copy (for further editing), to specify rules for the profile or to delete it.

Profiles

Create new

If no profile is set for the patient, the system default profile will be used.

Patient profiles

Name	Is default	
Athlete	<input type="checkbox"/>	Set Default Edit Copy Rules Delete
Elderly	<input type="checkbox"/>	Set Default Edit Copy Rules Delete

General profiles

No data available!

[Back to list](#)

Figure 25: Profiles page.

The active link “Create new” button is used to create a new profile. If clicked, the form to create a profile is presented in Figure 26. You can enter the new profile's name and click the check box if it is a default profile. To finalize this form, you need to click on the “Create” active button. Click the “back” link to cancel this operation and create a profile.

Create Alert Profile

Name

Is Default ☐

Create

[Back](#)

Figure 26: Create a new profile form.

Edit Alert Profile

Name

Is Default ☐

Save

[Back](#)

Figure 27: Edit a profile.

The created profile can be edited if the corresponding link is selected next to it in the list of profiles. Then, an edit form for a selected profile is shown in Figure 27. To finalize the editing, click the “Save” button or select “Back” to cancel the operation.

Rules

The list of predefined alert rules that can be imported into a profile by a form in Figure 28.

Profile Rules - Hospitalised

[Create Episode Rule](#) |
 [Create Beat Rule](#) |
 [Create QT Rule](#) |
 [Create Pause Rule](#)

Episode

Priority	Name	Minimum Duration	Minimum BPM	Maximum BPM	
LOW	SBR (Sinus bradycardia)	30 sec.		45	Edit Delete
LOW	SVTA (Supraventricular tachyarrhythmia)	30 sec.	120		Edit Delete
LOW	AFIB (Atrial fibrillation)	6 sec.	100		Edit Delete
LOW	AFL (Atrial flutter)	6 sec.	100		Edit Delete
LOW	B (Ventricular bigeminy)	6 sec.			Edit Delete
LOW	T (Ventricular trigeminy)	6 sec.			Edit Delete
MEDIUM	SBR (Sinus bradycardia)	15 sec.		45	Edit Delete
MEDIUM	SVTA (Supraventricular tachyarrhythmia)	15 sec.	150		Edit Delete
MEDIUM	AFIB (Atrial fibrillation)	30 sec.	100		Edit Delete
MEDIUM	AFL (Atrial flutter)	30 sec.	100		Edit Delete
MEDIUM	VT (Ventricular tachycardia)	2 sec.	100		Edit Delete
HIGH	SBR (Sinus bradycardia)	3 sec.		35	Edit Delete
HIGH	SVTA (Supraventricular tachyarrhythmia)	3 sec.	200		Edit Delete
HIGH	AFIB (Atrial fibrillation)	30 sec.	150		Edit Delete
HIGH	AFL (Atrial flutter)	30 sec.	150		Edit Delete
HIGH	VT (Ventricular tachycardia)	3 sec.	180		Edit Delete
HIGH	VFIB (Ventricular fibrillation)	3 sec.			Edit Delete
HIGH	VFL (Ventricular flutter)	3 sec.			Edit Delete

Beat Type

Priority	Name	Minimum Duration	Minimum Occurrence	
MEDIUM	V (PVC)	1 Minute	15	Edit Delete

QT

Priority	Sex	Period	QTc Bazzet Short	QTc Bazzet Long	QTc Fridericia Short	QTc Fridericia Long	QTc Framingham Short	QTc Framingham Long	
LOW	General	General	320 ms.	480 ms.	320 ms.	480 ms.	320 ms.	480 ms.	Edit Delete

Pause

Priority	Minimum Duration	
MEDIUM	25 sec.	Edit Delete
HIGH	3 sec.	Edit Delete

[Back](#)

Figure 28: Import profile rules.

The list of thresholds and alert rules for a selected profile is shown in Figure 29.

Profile Rules - Athlete

[Create Episode Rule](#) | [Create Beat Rule](#) | [Create QT Rule](#) | [Create Pause Rule](#)

Priority	Name	Minimum Duration	Minimum BPM	Maximum BPM	
LOW	SBR (Sinus bradycardia)	10 sec.		40	Edit Delete

[Back](#)

Figure 29: List of thresholds for a selected profile.

The list presents the priority (risk level) name and specified thresholds, followed by two links to edit and delete the rule. By clicking on the “Edit” link, an alert rule can be edited using the form presented in Figure 30. Clicking the “Save” button will save the changes, and selecting the “Back” link will cancel the editing operation.

Edit alert rule - Athlete

Raise LOW (Make a visit to a doctor within 3 days) alert for the rhythm episode SBR (Sinus)

if minimum duration is 10 seconds

average heart rate in the sequence is < 40 bpm

Active ☒

[Save](#)

* If you don't want to set a value for any field, then leave it empty.

[Back to list](#)

Figure 30: Edit an alert rule.

Clicking on the delete link can be used to delete an alert rule. Figure 31 presents a confirmation form for deletion. Clicking on the “Delete” button will permanently delete the rule, and clicking the link “Back to list” will cancel the deleting operation.

Delete Alert Rule - Athlete

Are you sure you want to delete this?

Priority	Low (Make a visit to a doctor within 3 days)
Episode	SBR
Minimum Duration	10 Seconds
Minimum BPM	
Maximum BPM	40
Active	<input checked="" type="checkbox"/>
Added by	Демо Доктор
Date Added	09.02.2022 18:15:03

Recalculate existing alerts? ☐

* Alerts will be recalculated in the background. The time for recalculation depends on the measurements period. Changes may not be visible immediately.

[Delete](#) | [Back to list](#)

Figure 31: Delete an alert rule.

Creating New Rules

Clicking the “Create Episode Rule” button on the list of rules will activate a form to create an alert rule specifying thresholds for a rhythm episode, as presented in Figure 32.

Create Alert Rule - Athlete

Raise

Select Risk Level

▼

alert for the rhythm episode

Select ...

▼

if minimum duration is

30

seconds

average heart rate in the sequence is

<

▼

bpm

Active

☒

Create

* If you don't want to set a value for any field, then leave it empty.

Back to list

Figure 32: Create an alert rule for a rhythm episode.

As presented in Figure 33, the risk level can be selected from three different values: LOW, MEDIUM, and HIGH.

Create Alert Rule - Athlete

Raise

Select Risk Level

LOW (Make a visit to a doctor within 3 days)

MEDIUM (Make a visit to a doctor within 24 hours)

HIGH (Make a visit to a doctor immediately!!!)

ie rhythm episode

Select ...

▼

if minim

average heart rate in the sequence is

<

▼

bpm

Active

☒

Create

* If you don't want to set a value for any field, then leave it empty.

Back to list

Figure 33: Select a risk level to be raised.

Figure 34 presents the list of possible rhythm episodes to be selected to set a threshold value for an alert rule.

Create Alert Rule - Athlete

Raise alert for the rhythm episode

if minimum duration is seconds

average heart rate in the sequence is bpm

Active ☒

* If you don't want to set a value for any field, then leave it empty.

[Back to list](#)

✓ Select . . .

- AFIB (Atrial fibrillation)
- AFL (Atrial flutter)
- B (Ventricular bigeminy)
- BI (2° Heart block)
- SBR (Sinus bradycardia)
- SVTA (Supraventricular tachyarrhythmia)
- T (Ventricular trigeminy)
- VFL (Ventricular flutter)
- VT (Ventricular tachycardia)
- VFIB (Ventricular fibrillation)
- SVT (Sinus tachycardia)
- AT (Atrial trigeminy)

Figure 34: Select a rhythm episode for the alert rule.

Figure 35 presents a form for creating an alert rule specifying thresholds for a heartbeat type. Clicking the “Create Beat Rule” button on the list of rules activates the form.

Create Alert Rule - Athlete

Raise alert for beat

if minimum occurrence in minute is

Active ☒

[Back to list](#)

✓ Select . . .

- N (Normal)
- A (PAC)
- V (PVC)
- a (AAPB)
- J (NPB)
- F (FVNB)
- E (VEB)

Figure 35: Create an alert rule for a heartbeat type.

Figure 36 presents a form for creating an alert rule specifying thresholds for a QT interval type. Clicking the “Create QT Rule” button on the list of rules activates the form.

Create Alert Rule - Athlete

Raise an alert for QT with risk level

Select Risk Level

for gender

General

and period of day

General

If QTc Bazett is less than

320

milliseconds

If QTc Bazett is greater than

480

milliseconds

If QTc Fridericia is less than

320

milliseconds

If QTc Fridericia is greater than

480

milliseconds

If QTc Framingham is less than

320

milliseconds

If QTc Framingham is greater than

480

milliseconds

Active

☒

Create

[Back to list](#)

Figure 36: Create an alert rule for a QT segment type.

Clicking the “Create Pause Rule” button on the list of rules will activate a form to create an alert rule specifying thresholds for a pause, presented in Figure 37.

Create Alert Rule - Athlete

Pause with risk level

Select Risk Level

if minimum duration is

2

seconds

Active

☒

Create

[Back to list](#)

Figure 37: Create an alert rule for a pause.

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5. How to Use the Monitoring Tools

The monitoring tools are activated by clicking the “Monitor” link accompanying a patient on the doctor’s home page or by clicking the monitor menu option when the doctor accesses the patient's events or reports.

5.1. Main Monitoring Page

Page Overview

When the monitoring tools are invoked, the system displays the main monitoring page (Figure 38).

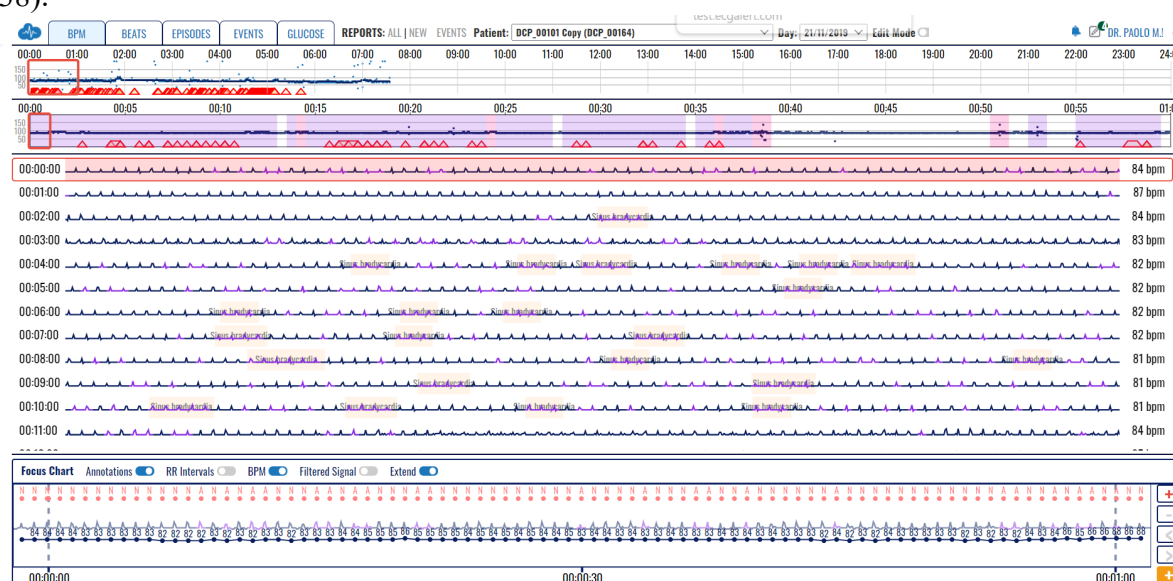


Figure 38: Main monitoring page.

It offers several functions and features listed in the following sections.

Basic Functions

The essential monitoring tools include:

- Display of heart rate series;
- Display of dashboard information;
- Navigation through ECG strips;
- Identification of detected beat types;
- Identification of detected rhythm episodes;
- Focusing on a particular ECG strip and its details;
- Adding selected ECG strips to reports;
- Analyzing details on detected arrhythmias;
- Managing the system setup of the monitoring tools;
- Selection of particular ECG section and editing its rhythm episode type; and
- Preview of events.

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Basic Graphical Sections

The “Main monitoring” page (Figure 39) is made up of four main sections:

- Monitoring header:
- BPM, Beats, Episodes or Events navigator:
- List of ECG strips and
- Focus chart.

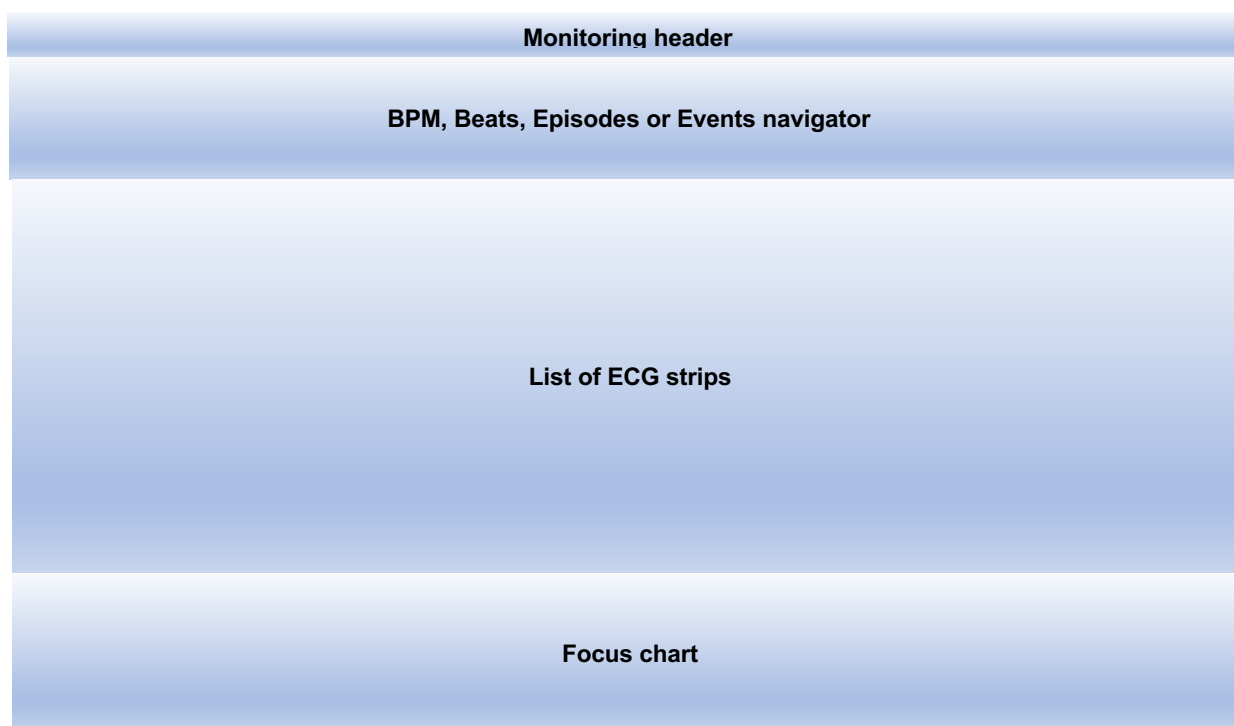


Figure 39: Main graphical sections.

The left part of the monitoring header contains links to the most used functions and menu options, including a toggle switch between bpm, beats, episodes, and events information for more straightforward navigation, links to completed reports, newly drafted reports, and events accompanied to the selected patient, forms to choose another patient or another date and editing mode to edit episode types.

The right part of the monitoring header contains links to system notifications, links to draft reports that were not completed, the doctor's name, and the settings drop-down menu.

The second section displays the bpm using the time series, beats, or episode information.

The third section displays a list of ECG strips and information about the calculated average BPM for each strip.

The final section is devoted to the focus chart, which is used to analyze details on a selected part of the ECG strip. It contains sophisticated tools for analyzing ECGs.

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5.2. Monitoring header

The monitoring header replaces the standard web application header and displays additional features and functionalities.

Home Icon

By clicking the “ViewECG icon” in the top leftmost corner (Figure 40), the user is redirected to the doctor’s home page.



Figure 40: The ViewECG icon acts as a home page link.

Choose a Patient

By clicking the “Patient’s name” (Figure 41), a drop-down list appears with all the patients assigned to the doctor. A click on a selected list item redirects the doctor to a monitoring page displaying the most recent record of the newly selected patient.



Figure 41: Choose a patient for monitoring.

Choose a Date

By clicking on “Date” (Figure 42), a drop-down list displaying all the days a patient has taken measurements appears. By changing the selected list item, the doctor is redirected to the newly selected day record.



Figure 42: Choose a date for monitoring.

Edit Mode

By clicking on the “Edit mode” switch (Figure 43), you can toggle between the option to edit the automatic diagnosis provided by the software or manually add new episodes of arrhythmias.



Figure 43: Edit mode toggle switch

System Notifications

The “Alarm icon” (Figure 5) used for system notifications is explained earlier.

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5.3. Menu Options and Links

Menu options and links include records used to display previously electronic health records and events to display critical moments when the patient marked the recording.

Reports

The “All” link (Figure 44) from the reports label displays a list of completed reports for the selected patient, and the “New” link displayed next to it goes to the drafted report for a patient if it has been created or to create a new draft report for the patient if it hasn't.



Figure 44: Link to completed reports (electronic health record) for the selected patient.

Events

The “Events” link (Figure 45) lists the events the patient specified while wearing the wireless sensor.



Figure 45: Link to events for the selected patient.

All Draft Reports

The “Draft reports” icon, located next to the alarm icon (Figure 46), displays the list of draft reports for all patients. The indicating number shows how many drafts the doctor has started but not completed yet. If there are no draft reports, the draft report icon will not be displayed.



Figure 46: One draft report notification.

Username and Settings

The username and settings icon at the top right corner (Figure 47) is used to log off, change user profile information, or set the settings for monitoring tools.



Figure 47: Settings option.

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Monitoring Settings

The monitoring settings menu (Figure 48) is exclusive to the monitoring page and appears as a subsection of the settings menu. The monitoring settings menu features the following settings:

- Diagnoses radio button set: toggles the display of annotation and episode areas in the monitoring interfaces; can be either set to on or off;
- Full-minute radio button set: toggles the duration of the ECG strips for the list of ECG strips section and the focus chart section; can be either set to on or off;
- Histogram scaling radio button set: toggles the scaling to either absolute or relative;
- histogram chart type radio button set: toggles the chart type either to bar chart or line chart;
- Histogram domain radio button set: toggles the domain either to count or percent and
- Episode histogram radio button set: toggles the episode histogram information domain to count or duration.

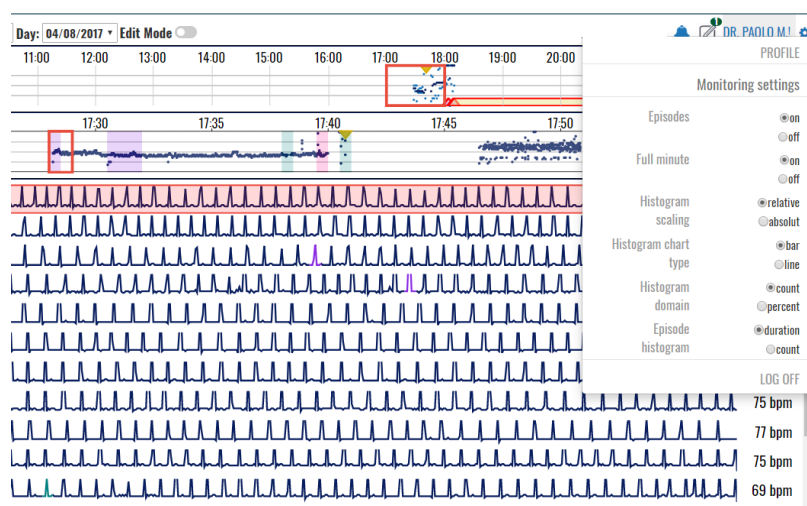


Figure 48: Settings page of the monitoring page.

5.4. BPM Navigator

The selector toggle switch enables the selection of the navigator type (bpm, beats, episodes, and events). If the bpm navigator is selected, two navigators are displayed: the hour navigator and the ECG strip selector. The heart rate navigator enables visualization of heart rate over a given time frame and easy navigation. It contains information on the distribution of heart rate globally in the day (the upper part is the hour navigator) or in an hour (the lower part is the ECG strip selector).

Hour Navigator

The hour heart rate series navigator (Figure 49) is divided into 24 subsections, each corresponding to one hour within the day. Time indicators display the hours. Only the realized measurements are displayed, and the missing parts are empty.

A red rectangle surrounding one of the hourly sections indicates the current hour on display. The red rectangle is set to the first hour of realized measurement during the day by default. By clicking one of the sections, the hour context is changed according to the clicked section; therefore, this navigator acts as a selector of a corresponding hour to be displayed.



Figure 49: Hour selector.

The hour navigator (selector) represents a heart rate chart. Each displayed pixel corresponds to a specific small interval in the hour navigator.

Three points are displayed for each pixel of the hour navigator: the average heart rate for the time interval corresponding to the pixel, a point drawn in a dark navy color, and a light blue point for both the minimum and maximum rate values within the corresponding interval.

The hour selector has three horizontal lines spanning throughout it, corresponding to heart rates of 50, 100, and 150 BPM. The line values are placed on the left side of the hour selector. The total chart interval is between heart rates of 0 and 200 BPM. If a point on the chart exceeds the interval, it will be displayed as a 200 BPM value.

Indicators for detected episodes are represented as trapezoids aligned with the bottom of the hour selector. The fill color corresponds with the episode color indicator. The indicators are set to the start and end time of the detected rhythm episode. In case of a detected episode, the mouse over shows a popup tooltip containing information for all the episodes present in the particular hour segment. The provided information comprises a time stamp of the episode start, the name of the episode, and the duration of the episode.

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ECG Strip Selector

The ECG strip selector (Figure 50) displays more detailed heart rate information for the selected hour. The length of the ECG strip can be 30 or 60 seconds, and the user can choose between strips with a duration of half or full minutes via the monitoring settings section in the Settings page.

If half-minute (30 sec) ECG strips are selected, the ECG strip selector is divided into 120 subsections, each corresponding to one half-minute (30 sec) interval within the current hour. If the setting is one full minute, the granularity of the ECG strip selector sections changes to 60 selectable sections in total, one for each minute.

The ECG strip selector has time indicators, one for each 5-minute interval.

A red rectangle surrounding one of the ECG strip selector sections indicates the current displayed interval. By clicking on a location of interest, the clicked section changes this interval context.

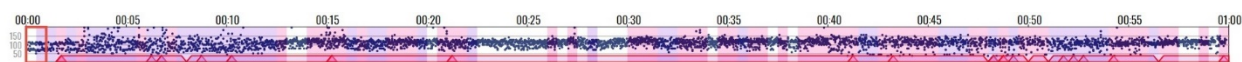


Figure 50: ECG strip selector.

The ECG strip selector represents a heart rate chart. Three points are drawn for each pixel, representing a heart rate value calculated for the corresponding time interval. All these points are dark navy.

Three horizontal lines span the ECG strip, with heart rate values of 50, 100, and 150 BPM. The line values are displayed on the left side of the hour selector. The heart rate chart interval is between 0 and 200 BPM. If a point on the chart exceeds the interval, it will be displayed as a 200 BPM value.

Detected rhythm episodes are indicated by trapezoids aligned with the bottom of the ECG strip selector. The fill color of these identifiers corresponds to the rhythm episode color indicator. The indicators are temporally set to indicate the start and end of the episode.

A mouse over a particular detected rhythm episode identification results in a popup tooltip that contains information. This information comprises a timestamp of the episode starts, its rhythm identification, and the duration for every episode in the selected segment.

The background of each ECG strip section representation is colored according to the color of the present annotation in the segment. If there are multiple annotations within an ECG strip section segment, the color will match the color of the first annotation.

5.5. List of ECG Strips

The central part of the monitoring tools is the list of ECG strips.

Displaying the List

The list of ECG strips (Figure 51, Figure 52) contains 120 ECG strips with a duration of 30 seconds or 60 ECG strips with a duration of 60 seconds, per the chosen setting. ECG strips are presented in each row of the list. The information on the start of the ECG strip is on the left, and the average heart rate is on the right. Empty strips display "NaN" instead. The displayed ECG strip is not the actual ECG signal but a signal filtered using a band-pass filter in the range [0.5Hz, 30Hz] with a filter length of 0.2s to eliminate the baseline drift or high-frequency noise. Therefore, it is expected that the displayed strip is somehow a modified version of the original recording, but an experienced doctor can notify all related arrhythmia on this signal more quickly than on the original recording. The focus chart analyzes the original signal and determines its features. These ECG strips are just a quick indication for faster analysis.

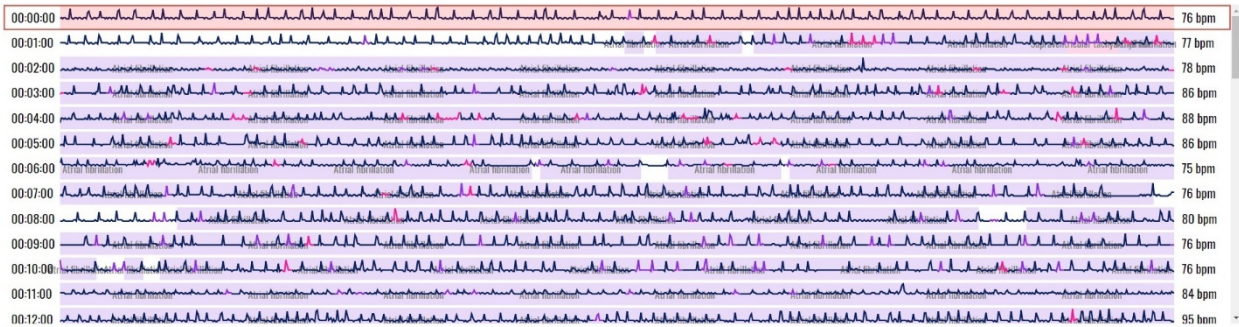


Figure 51: List of ECG strips.

One ECG strip is indicated by a red-bordered rectangle around the line (Figure 52). This ECG strip is also presented in the focus chart for easier monitoring with more sophisticated tools, including analysis of RR intervals, detailed heart rate for the given ECG strip, the initial original ECG recording (unfiltered signal), grid, scaling, and other features, such as zoom or navigation. A semi-transparent rectangle is drawn behind the ECG signal, indicating the position of the ECG strip in the focus chart section. If a zoom option is used in the focus chart, then only a part of the ECG strip is marked by this semi-transparent segment. All detected beat types are indicated in the ECG strip by a corresponding annotation color. The normal beat annotations are not marked or shown on the ECG strip. The detected episodes are marked on the strip by drawing a semi-transparent colored rectangle, matching the area affected by the color of the rhythm episode. Discretely, the title of the rhythm of the episode is written on the background of these rectangles behind the displayed ECG signal to avoid any misinterpretations. A click on a particular ECG strip will result in selecting this ECG strip, moving the colored red square around it, and displaying it in the focus chart. A double click on a particular item in the ECG strip will be identified as a zoom option for the focus chart. This will display an ECG strip with double magnification (2x). A consecutive double click will display a smaller ECG segment with doubled size (4x), and another click will even display the 8x magnification size.

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Navigating the List

The doctor can navigate the list of ECG strips by the vertical slider on the right side. A mouse “drag and drop” action can move the visible part of displayed ECG strips.

Vertical navigation is also possible using mouse scroll functions to scroll the list upwards or downwards.

Approaching the last visible ECG strip will load a new hour selection, which the doctor can navigate as a continuous list. Similarly, approaching the first ECG strip and scrolling upwards will load the ECG strips from the previous hour.

You can also use up and down or left and right keyboard buttons to navigate through ECG strips. These actions will correspondingly select the previous or next ECG strip, and the result will be displayed in the focus chart. It will also update the displayed list so the selected ECG strip is positioned in the middle of the screen.

Double-clicking a specific location on the ECG strip increases the magnification level on the focus chart, and the position indicator adjusts its position and size according to the new magnification level. The process can be repeated until the maximum magnification of 8 is reached. In the case of magnification, the position indicator (Figure 52) can be dragged to the left or right so that the focus chart horizontal offset is adjusted.

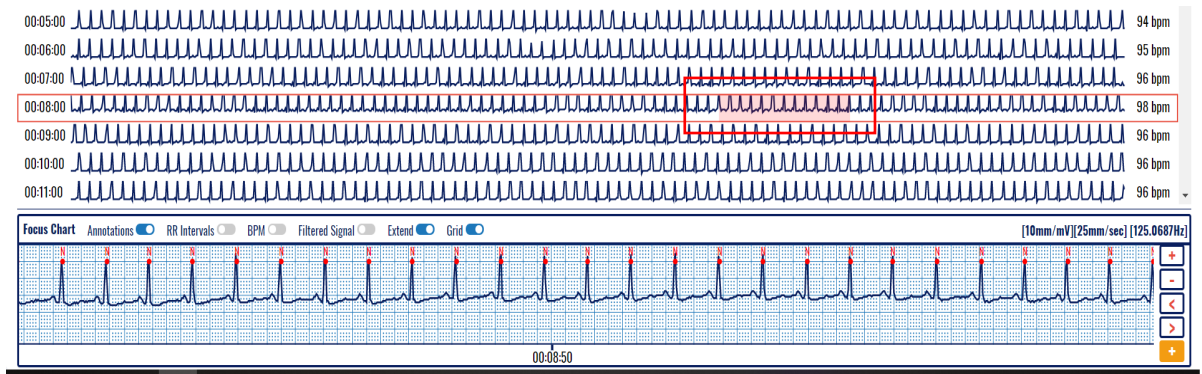


Figure 52: An ECG strip with a selected segment to be displayed in the focus chart.

5.6. Focus Chart

The selected ECG strip from the displayed list is presented in greater detail in the Focus chart (Figure 53). The default width of the focus chart is equal to the width of the ECG strip, but it can be magnified up to 8x zoom. The last two magnification levels (4x and 8x) can display a standard grid with 10 mm/mV and 25mm/sec (Figure 54).

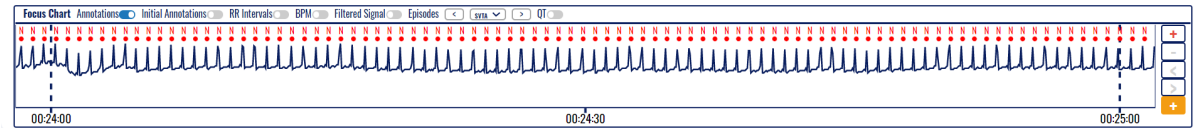


Figure 53: Focus chart.

The focus chart contains a header in the upper part, magnification control in the right part, and time-related information in the lower part. The central part visualizes the selected ECG segment.

The displayed ECG strip represents a filtered signal using a band-pass filter in the range [0.5Hz, 30Hz] with a filter length of 0.2s. This eliminates baseline drift and high-frequency noise. The doctor can activate a display of the original recording in addition to this representation to analyze the details of the ECG signal.

All detected beat types are indicated in the ECG strip by a corresponding annotation color (Figure 54). The normal beat annotations are not marked or shown on the ECG strip.

A semi-transparent colored rectangle on the focus chart may indicate a detected episode (Figure 54). To avoid misinterpretations, the title and rhythm of the episode are written discreetly on the background of these rectangles behind the displayed ECG signal.

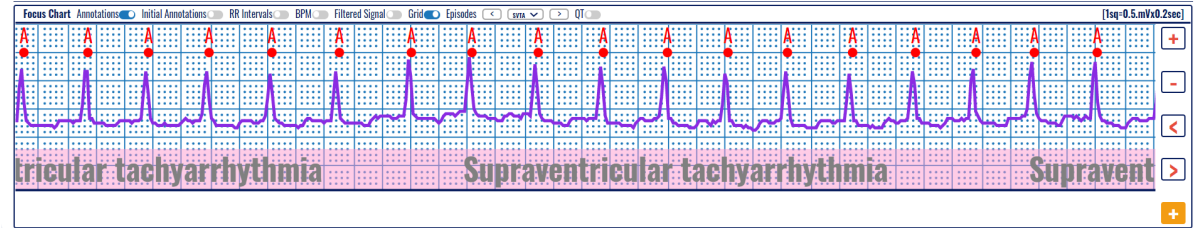


Figure 54: A focus chart with identified beats and rhythm episodes.

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Magnification Levels

There are four different levels of magnification:

- X1 – the focus chart visualization window fits the entire ECG strip (Figure 55);
- X2 – the focus chart visualization window fits to half the length of the ECG strip (Figure 56);
- X4 – the focus chart visualization window fits a fourth of the length of the entire ECG strip (Figure 57) and
- X8 – the focus chart visualization window fits an eighth of the length of the entire ECG strip, and the height of the focus chart is doubled for better visualization (Figure 58).

A double click on a particular location on the ECG strip or focus chart will result in doubling the magnification level of the displayed ECG in the focus chart. You can use the (+) and (-) navigation buttons to increase or decrease the magnification level.

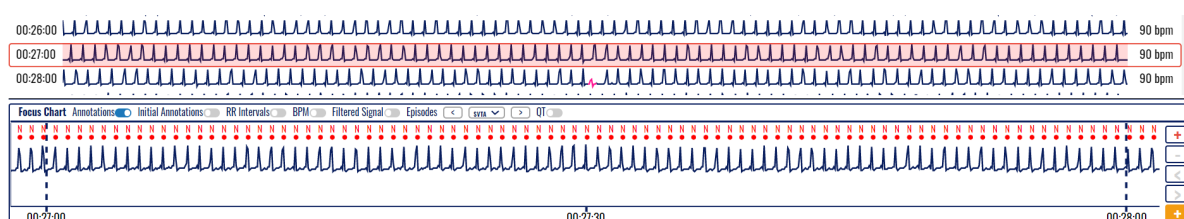


Figure 55: Selected ECG strip segment and focus chart presenting annotated beats.

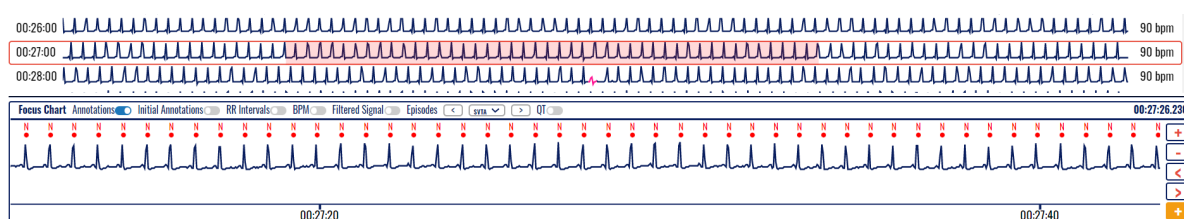


Figure 56: Selected ECG strip segment with 2x magnification and focus chart presenting annotated beats.

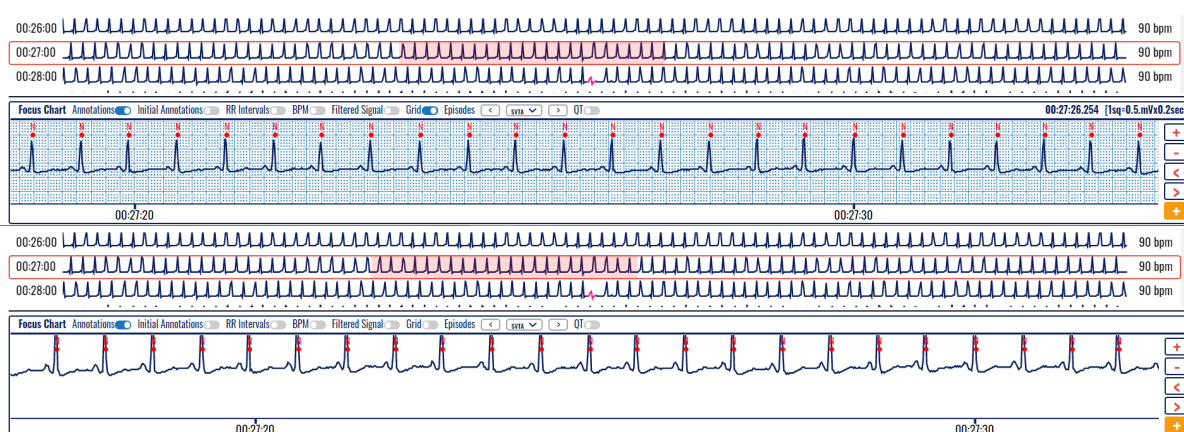


Figure 57: Selected ECG strip segment with 4x magnification and focus chart presenting annotated beats.

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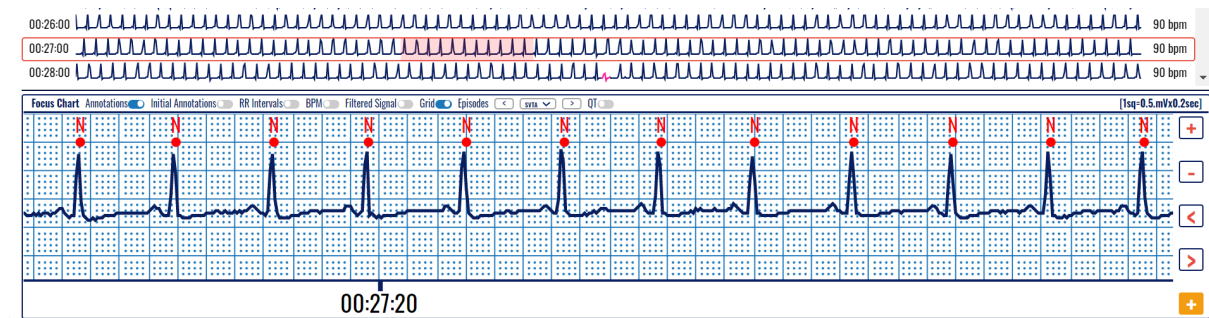


Figure 58: Selected ECG strip segment with 8x magnification and focus chart presenting annotated beats.

Time markings below the ECG strip are:

- In case of X1 magnification, the time markings are drawn for each 15s in case of half minute ECG strip and for each 30s in case of a full-minute ECG strip;
- In case of X2 magnification, the time markings are drawn for each 10s in case of half minute ECG strip and for each 20s in case of a full-minute ECG strip, and
- In the case of X4 or X8 magnification, the time markings are drawn for each 5s in a half-minute ECG strip and for each 10s in a full-minute ECG strip.

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Focus Chart Header

The focus chart header section, located above the ECG strip, contains a list of toggle controls that affect the displayed information on the focus chart:

- Annotations toggle – toggles the display of annotation markings above the identified wave components; default value: on;
- Initial Annotations toggle – toggles the display of initial annotation markings below the identified wave components; default value: off;
- RR intervals toggle – toggles the display of the duration of the RR intervals in seconds; default value: off;
- BPM toggle – toggles the display of BPM value for each RR interval; additionally, the values are interconnected and vary in height so that they form a chart on their own; default value: off;
- Filtered signal toggle – toggles the display of the original/initial/unfiltered signal in addition to the unfiltered signal; default value: off;
- Grid toggle – toggles the display of the grid. If a grid is displayed, the right part of the focus chart header represents information about the presented scale and sampling frequency. Available in case of X4 or X8 magnification;
- QT toggle – toggles the display of QTc values. In case the QT tab is open from the Main Menu, the display of QTc values can be toggled between Bazett, Fridericia, Framingham, and
- The episodes drop-down menu selects the available episodes and navigates between the previous and next ones.
- Episodes' navigation buttons (<) and (>) are used to navigate to the previous (left arrow) or next episode (right button)
- Fast episode deleting and navigation buttons (<X) and (X>) are used to delete the selected episode and navigate to the previous (left arrow) or next episode (right button)

Display of Grid and Beat Annotations

Annotations can be displayed by corresponding beat type identification over the red marked dot for detected heartbeats (Figure 59, Figure 60, Figure 64, and Figure 65). When annotations are not displayed, each detected heartbeat is marked only by a red dot (Figure 61, Figure 62, and Figure 63).

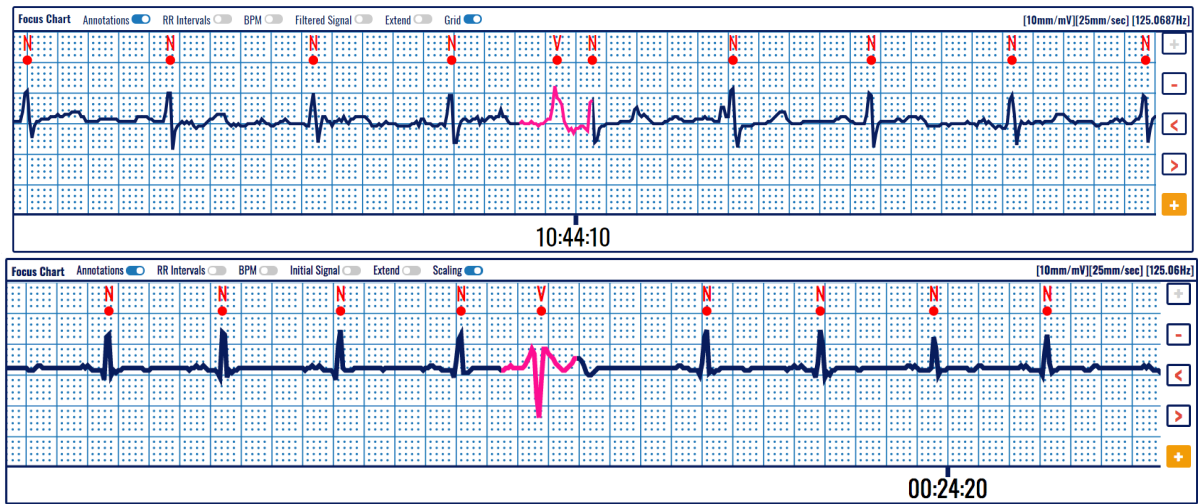


Figure 59: Focus chart presenting annotated beats of an ECG strip on a predefined grid.

A grid is usually used in ECG strips (Figure 59) to facilitate the calculation of distances between characteristic features, such as beat-to-beat distance (RR interval), PR or ST segment width, etc. When there is no grid, the displayed ECG (Figure 60) is scaled to the allowed height.

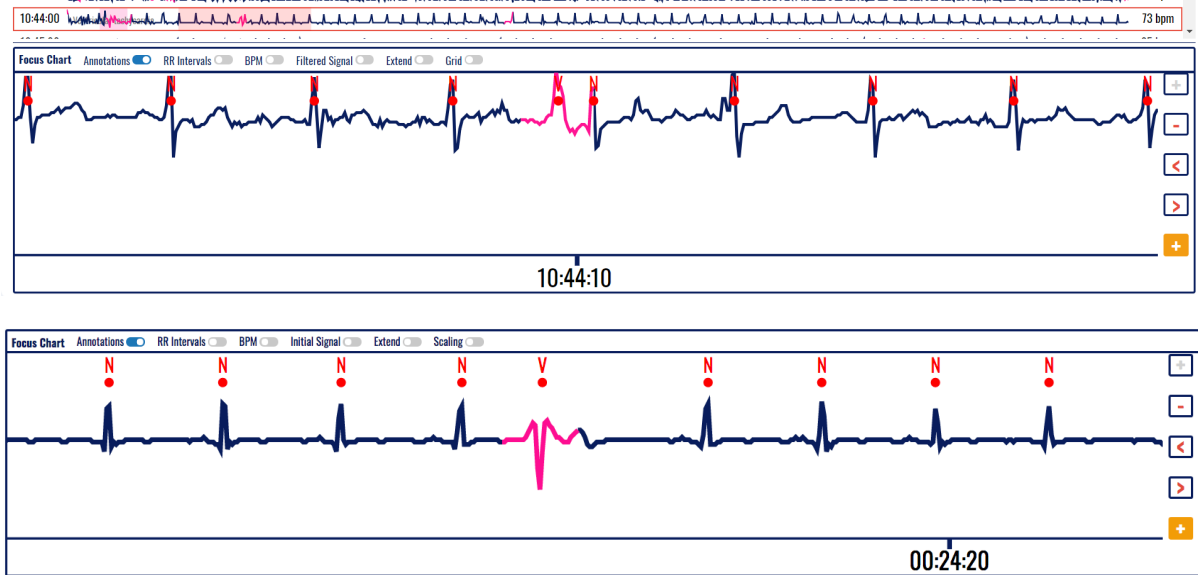


Figure 60: Focus chart of annotated ECG strip presented without a grid.



Figure 61: Focus chart presenting an ECG strip on a predefined grid.

Extended Heart Rate-related Info

When the corresponding toggle switch is activated, the RR intervals are displayed in seconds (Figure 62) to represent the distances between detected consecutive heartbeats.

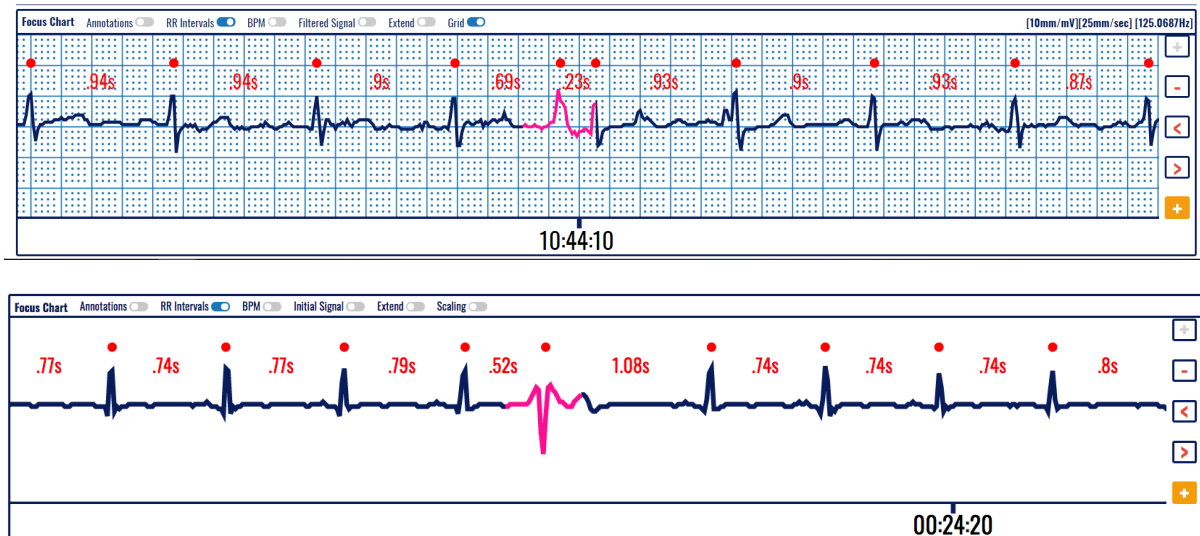


Figure 62: Focus chart without annotations, including the RR intervals.

The toggle switch on BPM displays a heart rate chart corresponding to each detected heartbeat. This chart shows current changes in the heart rate (Figure 63).

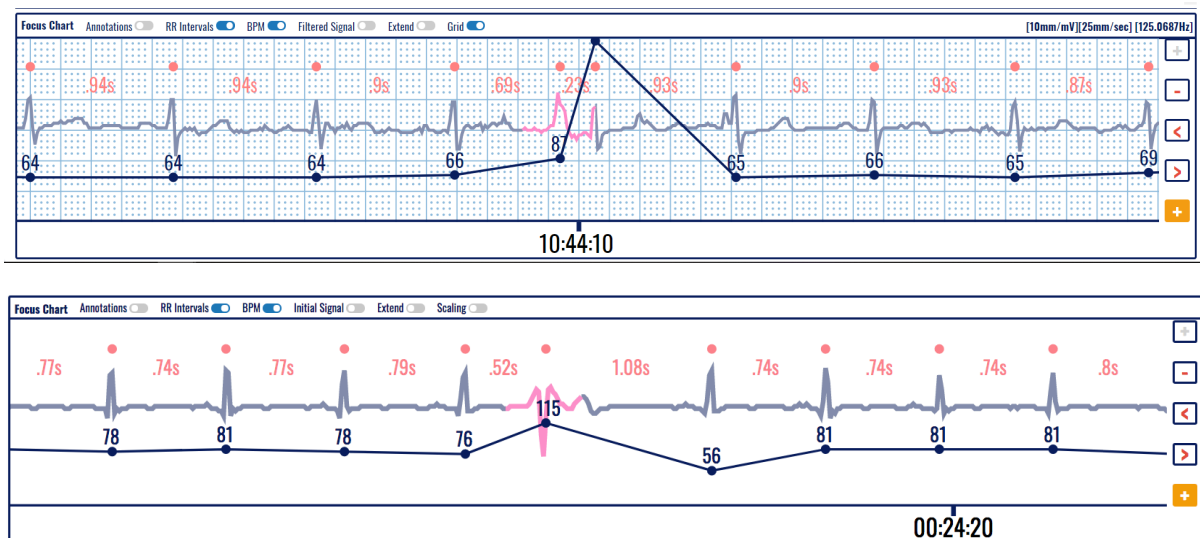


Figure 63: Heart rate information along with RR intervals on the focus chart.

Extended Visualization Features

The filtered ECG recording (Figure 64) is displayed when the corresponding toggle switch is activated. It is displayed on top of the original signal and can be used to identify the beat type or analyze rhythm episodes more easily.

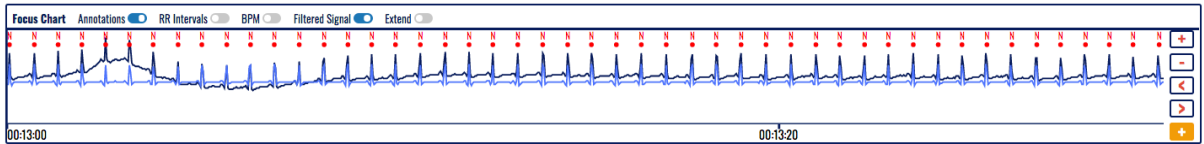


Figure 64: Filtered ECG recording presented on top of the annotated original signal with RR intervals.

Sometimes, a beat may occur at the very beginning or end of the ECG strip, and therefore, it is very difficult to analyze it in a broader context. The extend feature (Figure 65) allows for the extension of the visible part, so this beat can even be interpreted in the context of previous or next heartbeats. It is activated or deactivated by the corresponding toggle switch.

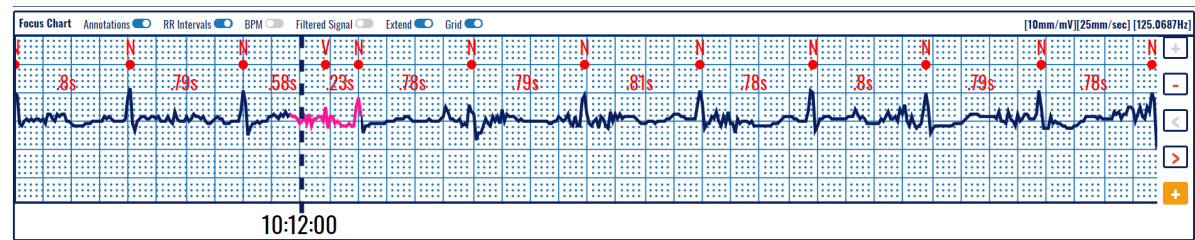


Figure 65: Extend segment function used on focus chart on a predefined grid.

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Magnification and Navigation

On the right side of the ECG strip in the focus chart, four control buttons assist the focus chart navigation and magnification:

- Zoom in button (+) - increases the magnification level;
- Zoom out button (-) - decreases the magnification level;
- Slide left button (<) - slides the strip to the left for one Nth of its length, where N is the magnification coefficient;
- Slide right button (>) - slides the strip to the right for one Nth of its length, where N is the magnification coefficient and
- Add a segment to report (+) on an orange background used for reporting.

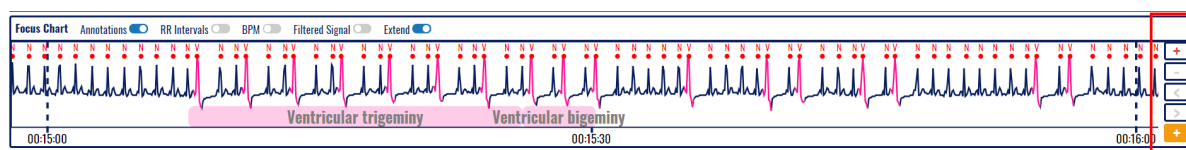


Figure 66: An extended display of the ECG in the focus chart (1 sec out of 30 sec borders).

The center point of the 7.5s ECG strip is the center point of the visible part of the ECG strip from the focus chart. The annotations not marked as normal are indicated on the ECG strip by coloring the area around the annotation with the corresponding annotation color. The detected episodes are marked on the ECG strip by drawing a semi-transparent colored rectangle, matching the area affected, and by discretely drawing the episode's title within the semi-transparent colored rectangle.

With the change of magnification, the semi-transparent selector from the currently selected ECG strip in the list of ECG strips changes its length to correspond to the focus chart's magnification level. If the magnification level is X4 or X8 and the scaling is turned on, the ECG grid mash is drawn behind the ECG signal, and the "[1sq=0.5mV x 0.2sec]" marking appears on the far right corner of the focus chart section header.

In a magnification level greater than X1, the focus chart can be dragged towards the left or right, changing its horizontal offset. Changing the horizontal offset of the focus chart, the semi-transparent selector from the currently selected ECG strip in the list of ECG strips changes its horizontal offset to correspond to the focus chart's horizontal offset.

A double click on the focus chart will double its current magnification level unless it is already at its maximum level.

Below the assistive navigation buttons, there is another button marked with (+) in orange background, which distinguishes it from the others. It adds an ECG strip with a duration of 7.5 seconds for the report generation.

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QT Interval

Selecting the QT button from the Focus Chart will display QT intervals, as in Figure 67. The background will be colored green if the calculated QTc value, according to the Bazett formula, results in a QT interval in a normal range or an orange background if it is longer or shorter than the normal range.

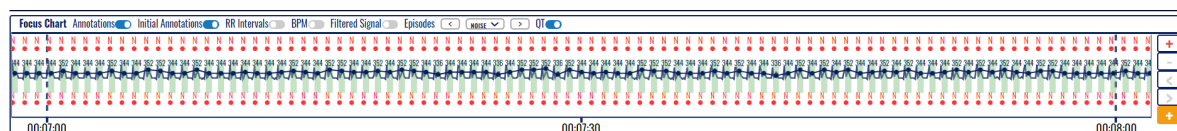


Figure 67: QT in Focus Chart.

Figure 68 presents a zoomed portion of the Focus chart with displayed QT intervals. Note that the software might detect noise, such as in the second QRS, and will not calculate the QT interval (the negative pick after the T-wave corrupts the signal and adequately identifies the end of the T-wave). The other QT intervals are correctly calculated. Two values over the green background indicate the measured QT and the calculated QTc with the Bazett formula; for example, 328/389 correspond to the measured QT/calculated QTc values.

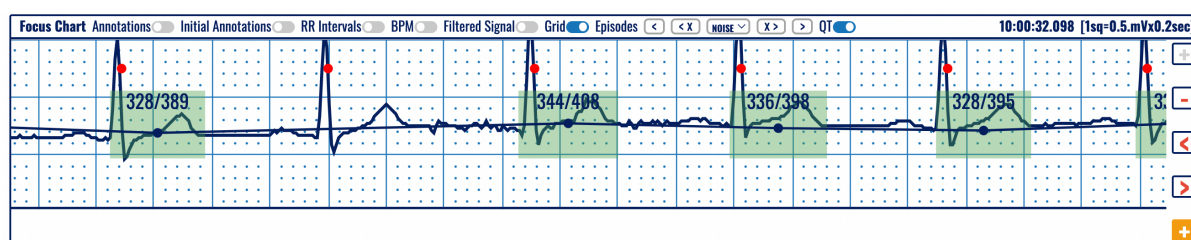


Figure 68: Detection of normal QT intervals (green background) in the Focus Chart.

Detection of QT intervals out of the normal range is displayed on an orange background. For example, Figure 69 presents a long QT interval calculated according to the Bazett formula (measured QT is 520 and calculated QTc is 486).

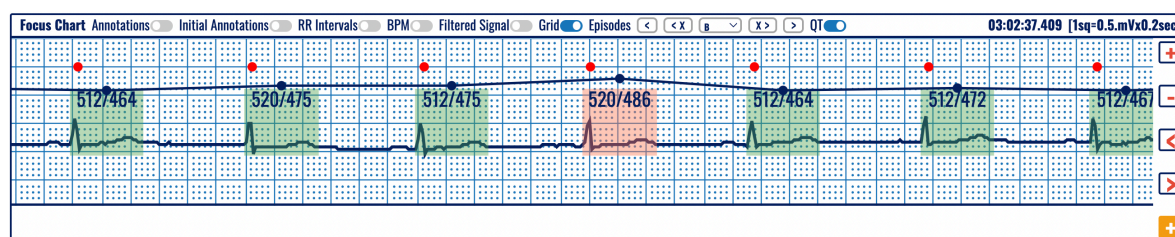


Figure 69: Detection of a long QT interval (orange background) in the Focus Chart.

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5.7. Edit Mode

The edit mode is toggled by clicking on the “Edit mode” toggle switch in the monitoring header section (Figure 43).

The Edit mode is used when a doctor wants to make manual changes to the type of episodes detected automatically by the system or add a new arrhythmia episode that hasn't been detected by the system.

When the toggle switch is enabled, the list of ECG strips and the focus chart do not change visually, but the user can edit the list of ECG strips by using drag-and-drop actions.

The drag and drop function is activated when a doctor clicks and holds the left mouse click over a strip in the List of ECG strips section. Then, the user can drag the mouse to select the preferred area, and when he drops the mouse click, a dialog box appears (Figure 70). The box allows a doctor to add one of the following episode types to the selected section of the ECG strip: N, AB, AFIB, AFL, B, BII, IVR, NOD, P, PREX, SBR, SVTA, T, VFL, VT, NOISE.

The doctor can close the dialog box by canceling the action using the Cancel button, or he can select an episode and click the Add button to mark the selected ECG portion with an episode of his choosing.

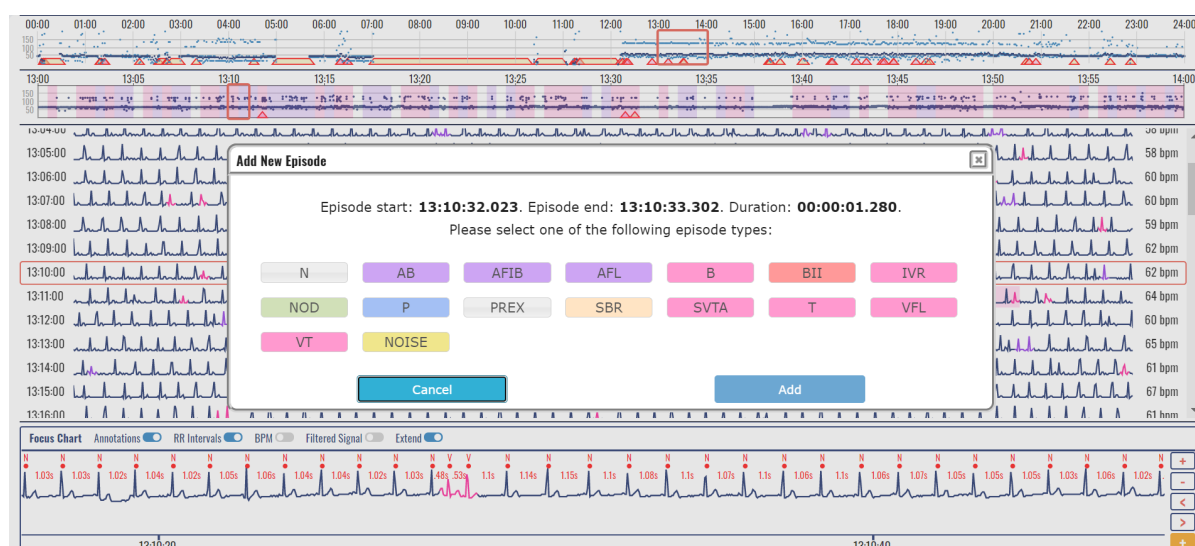


Figure 70: Edit mode's drag and drop function dialog box

If the user changes the annotations of the ECG records and then toggles the Edit mode button to disable it, an annotation changed prompt window appears that informs the user that the annotations have been successfully processed (Figure 71).

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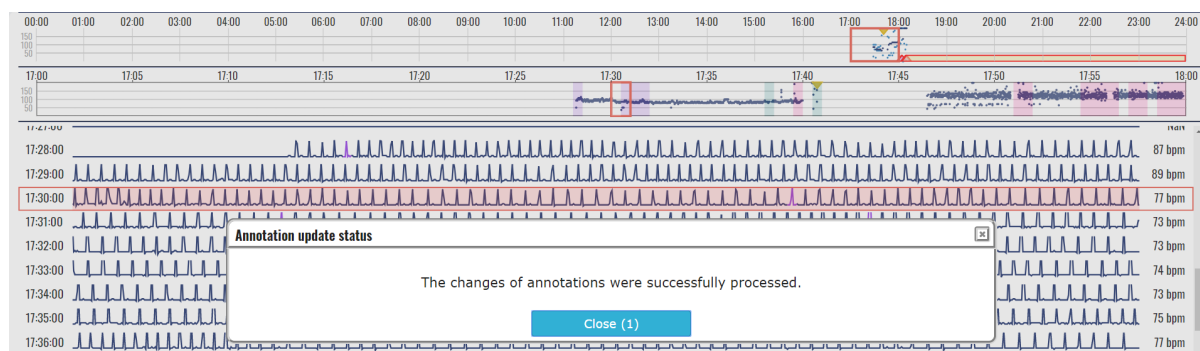


Figure 71: Annotation update status prompt

If the Edit mode is turned on and the user clicks the right mouse button over an episode, the right-click episode menu opens. The menu offers two options: edit the episode or delete it.

Upon clicking the edit episode menu item, a dialog window opens that looks like the one described in Figure 70 but allows the user to change the start and end time of the selected episode instead of only changing the episode type. If the user wants to update the file with the changes, he presses the Update button on the dialog box. If the user doesn't want to save the changes, he can abort the action by clicking the Cancel button.

Upon clicking on the delete episode menu item from the right-click context episode menu, a confirmation window opens, asking the user for confirmation on the desired action to delete the selected episode. The user can choose to delete the episode by clicking the "Delete" action button or to cancel his action by clicking the "Cancel" button.

If the Edit mode is turned on and the doctor tries to access the Beats or Episodes sections from the monitoring header navigator, the system prompts the doctor that this section cannot be accessed while the Edit mode is on. A confirmation dialog window is displayed with a question about saving the changes made in edit mode or canceling the changes. Clicking on "Continue" will exit Edit mode and continue to the Beats or Episodes sections. Clicking "Cancel" will remain in the BPM section with enabled Editing mode (Figure 72).

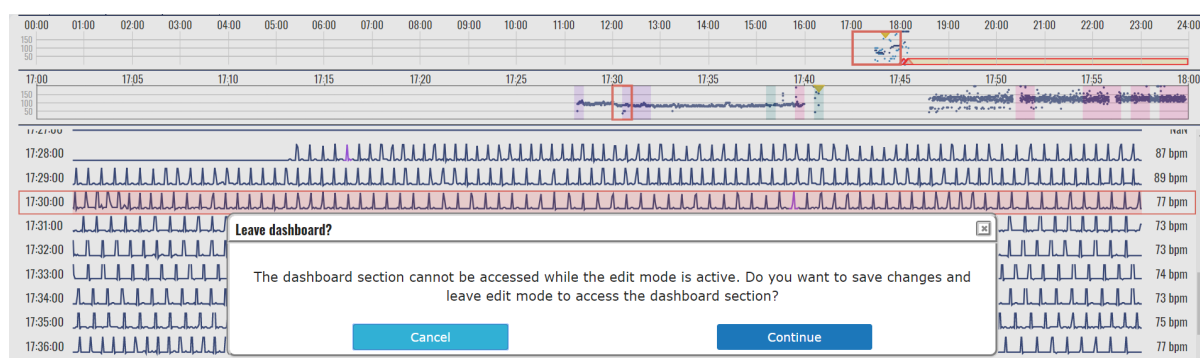


Figure 72: Leaving Monitoring section when Edit mode is enabled prompt window

When the doctor tries to enter Edit mode, and the Beats or Episodes section is selected in the navigation from the monitoring header, the system displays a dialog box prompting the user that Edit mode is unavailable in the selected section. To continue to edit mode, the doctor has to exit the current section (Figure 80).

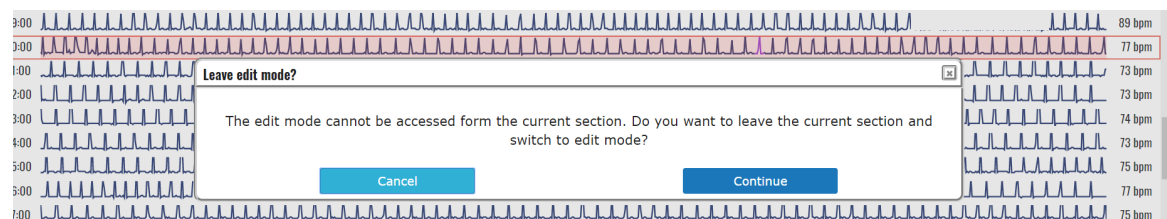


Figure 73: Prompt when a user tries to enter Edit mode from the Beats or Episodes section

The edit mode supports drag-and-drop and right-click interaction events. Therefore, the doctors can add, edit, and delete episodes directly from the focus chart. The drag and drop features work while having the Shift button pressed down (Figure 74 and Figure 75). In case of leaving the page without exiting the edit mode, the doctor will be automatically prompted by the pop-up window for attempting to leave the monitoring page without saving the changes.

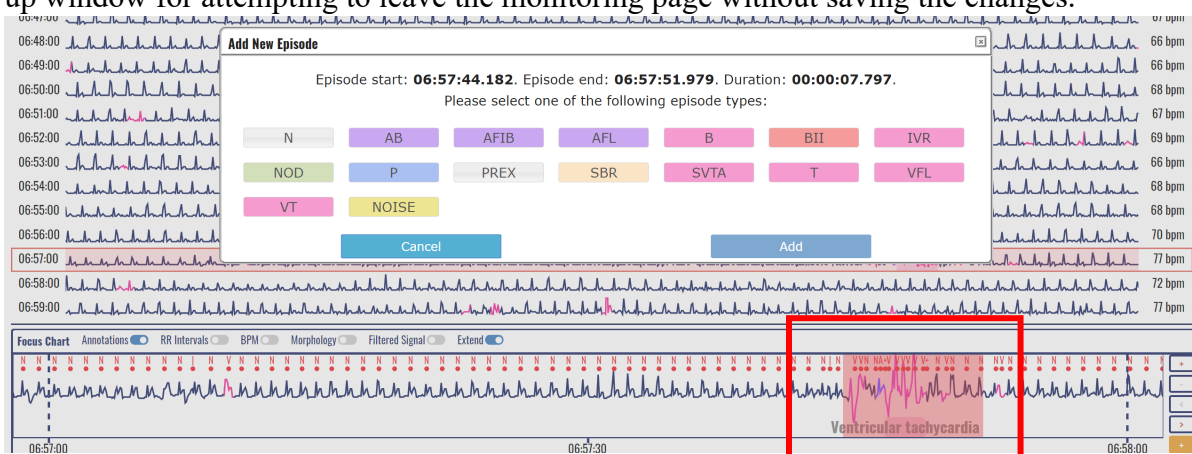


Figure 74: Segment selection for segment editing

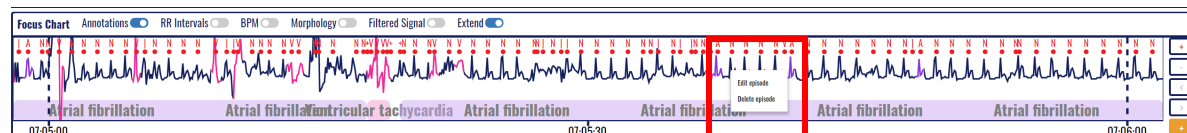


Figure 75: Segment selection with Shift function

The doctor can edit the beat annotations by opening the edit annotation pop-up window and pressing the Alt + Left click combo. The left click should be positioned somewhere in the focus chart section. To edit the beat annotations, the edit mode must be active. The content of the pop-up window is a copy of the content of the focus chart, positioned on a segment that matches the position of the click that opened the window. The doctor can horizontally slide the content of the pop-up window by dragging and dropping the interaction of the window content by clicking on anything but the annotations in the window (Figure 76).

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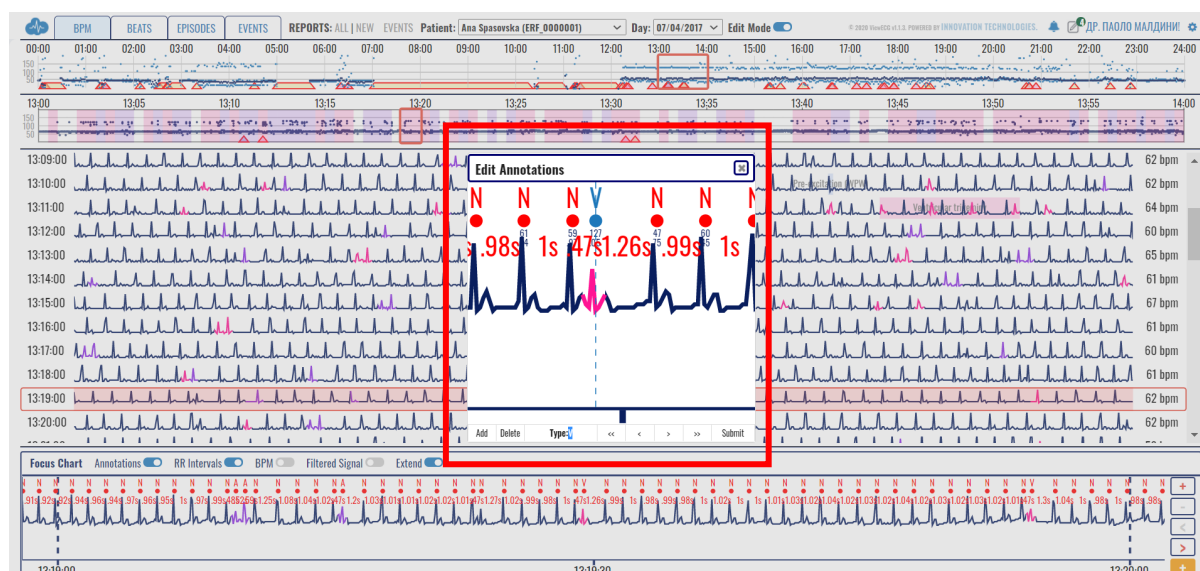


Figure 76: Beat annotation editing

The nearest annotation to the click is marked as ‘selected,’ meaning the changes will be applied. The selected annotation is blue in contrast to the red annotations. The doctor cannot select the ‘+’ annotation; instead, the nearest non- ‘+’ will be chosen. The exact positioning of the selected annotation is indicated with the help of a vertical dashed line.

The bottom of the pop-up window has the following controls:

Add – Adds a new beat annotation at the middle of the pop-up window, with the type ‘N.’

Delete – Deletes the selected annotation; the nearest beat annotation is selected after deletion.

Type – A textbox input control that changes the annotation type. If the unsupported annotation is entered in the textbox, the user is prompted by a pop-up box that the value is invalid.

<< - Selects the previous annotation in the focus chart segment of the same type as the currently selected.

< - Selects the previous annotation in the focus chart segment.

> - Selects the following annotation in the focus chart segment.

>> - Selects the following annotation in the focus chart segment of the same type as the currently selected.

Submit – Submits the changes done and the content of the focus chart is immediately updated.

The doctor can change the positioning of the selected annotation by drag and drop interaction on the selected annotation. Double-clicking the selected annotation is either re-positioned exactly in-between the neighboring annotations or is deleted (the decision to re-position or delete is AI-supported for achieving optimal editing).

Suppose you double-click on anything, but the beat annotations and beats in the corresponding RR interval at the double-click position are missing. In that case, they will be automatically added (AI-assisted feature).

There is a BPM preview for the current annotation and the neighboring four annotations to assist with the optimal positioning of the annotations (Figure 77). When the selected annotation is in an optimal position (the neighboring RR intervals result in a BPM difference of ≤ 3 BPM), the BPM preview values are colored green. They are bolded, in contrast to the default blue color of the BPM preview.

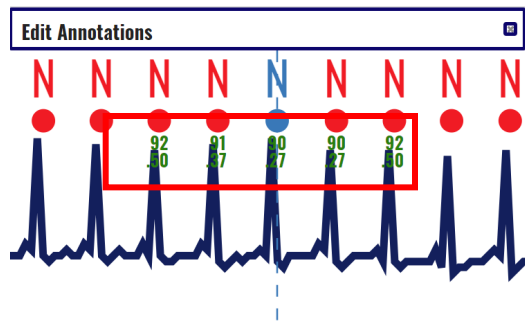


Figure 77: BPM preview

After submitting the annotation changes, the edit annotation window stays open for further editing. The user can close the window by pressing the Esc button or clicking the close window button in the top right corner of the pop-up window.

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5.8. Beats

The beats navigator is toggled between bpm, beats, episodes, events, QT, and alerts in the monitoring header section by clicking the toggle buttons.

The role of the Beats (Figure 78) is to provide quick access to information on detected beat types for a particular period and to navigate through appearances of detected arrhythmia beats. Additional visualization and monitoring tools are provided for detailed analysis of the detected arrhythmia.

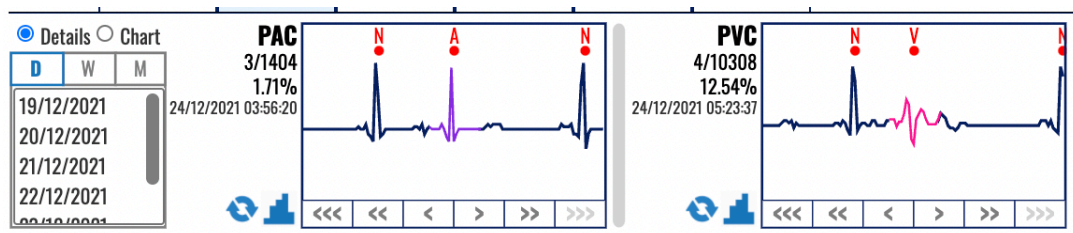


Figure 78: Beats navigator is displayed instead of an hour selector on the list of ECG strips.

The beats information appears in the same area of the hour selector and ECG strip selector sections combined.

It is divided into two sections:

- Control section – located on the left of the dashboard; contains the controls that determine the content of the content section and
- Content section – located on the right of the dashboard; contains statistics and quick access to the annotations for a selected period and information domain.

The control section (Figure 79) has one subsection and one radio button group:

- Period selector section (D, W, M) – located on the left side of the control section used to select the period for the content section; and
- Information domain selector (two radio buttons that form a group) – located on the top of the control section and is used to determine whether the content section will contain details about beat annotations or charts about them.

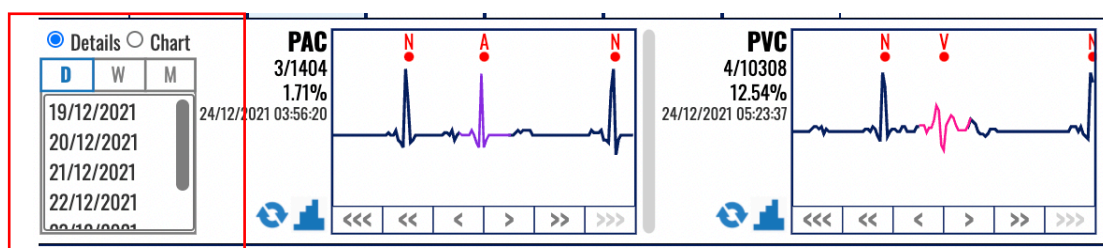


Figure 79: Control section of beats navigator.

The period selector section (left side of the control section, Figure 79) has a header on top and a list of date ranges. If there are more dates than those displayed in the list, there is a vertical navigation bar to navigate through the list.

The header is made up of a toggle switch with three options:

- Day toggle (D);
- Week toggle (W); and
- Month toggle (M).

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Only one toggle option can be active at a time. The summary information presented in the content section corresponds to the period selected by this toggle switch.

The list of dates contains available periods with duration by the active toggle option from the header. Only one list selection can be active at a given time.

The information domain selector has two radio buttons that form a radio button group and display the options Details and Chart. When the option “Details” is selected, the beats navigator's content section displays the annotated beats dashboard (Figure 80). When the option “Chart” is selected, the content section presents the annotation histograms of detected beat types (Figure 81).

The content section of the beats, located on the right side of the beats navigator (Figure 80), provides statistical information and quick access to the selected information domain (beat annotations) for a time period selected from the beats control panel.

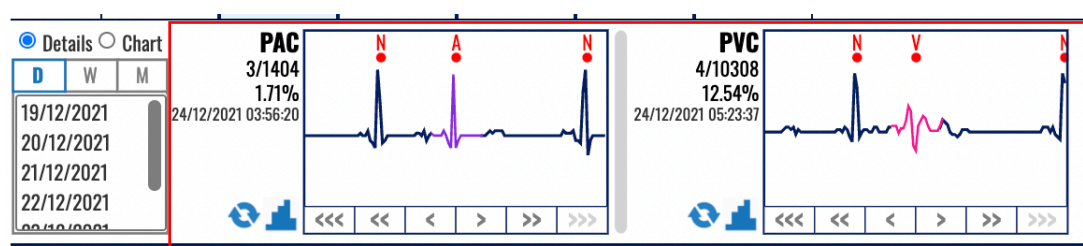


Figure 80: Content section of beats navigator representing dashboard of annotated beats.

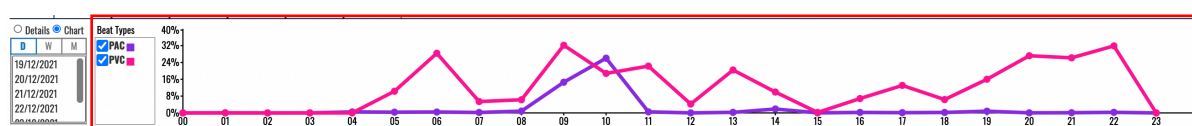


Figure 81: Content section of beats navigator representing annotation histograms.

Dashboard of Annotated Beats

This dashboard displays the annotated beats (Figure 80). When the information domain is set to details, the content section provides an information box (Figure 82) for each annotation detected in the selected period.

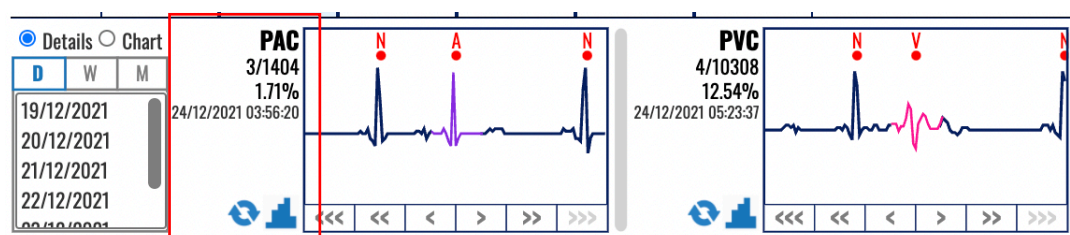


Figure 82: The information box is associated with each annotated beat type.

The information box contains:

- An abbreviated name of the annotation beat type that, on mouse over, displays tooltip information of the exact name of the annotation beat;
- Current identification and total number of beat type occurrences (the first number is the current beat identification and the second the total number of occurrences);
- Percentage of beat type occurrences relative to the total number of detected heartbeats (QRS waves) in the selected period;
- The date and timestamp of the currently displayed beat type;

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- Heart rate value derived from the displayed annotations expressed in BPM; and
- A column chart icon is a shortcut to the corresponding annotation histogram column chart (a shortcut for switching to the annotation histogram context of the content section).

A click in one of the display boxes representing the beat types will open the extended viewer in the central part instead of the list of ECG strips, as presented in Figure 83, to better visualize the detected arrhythmia beat.

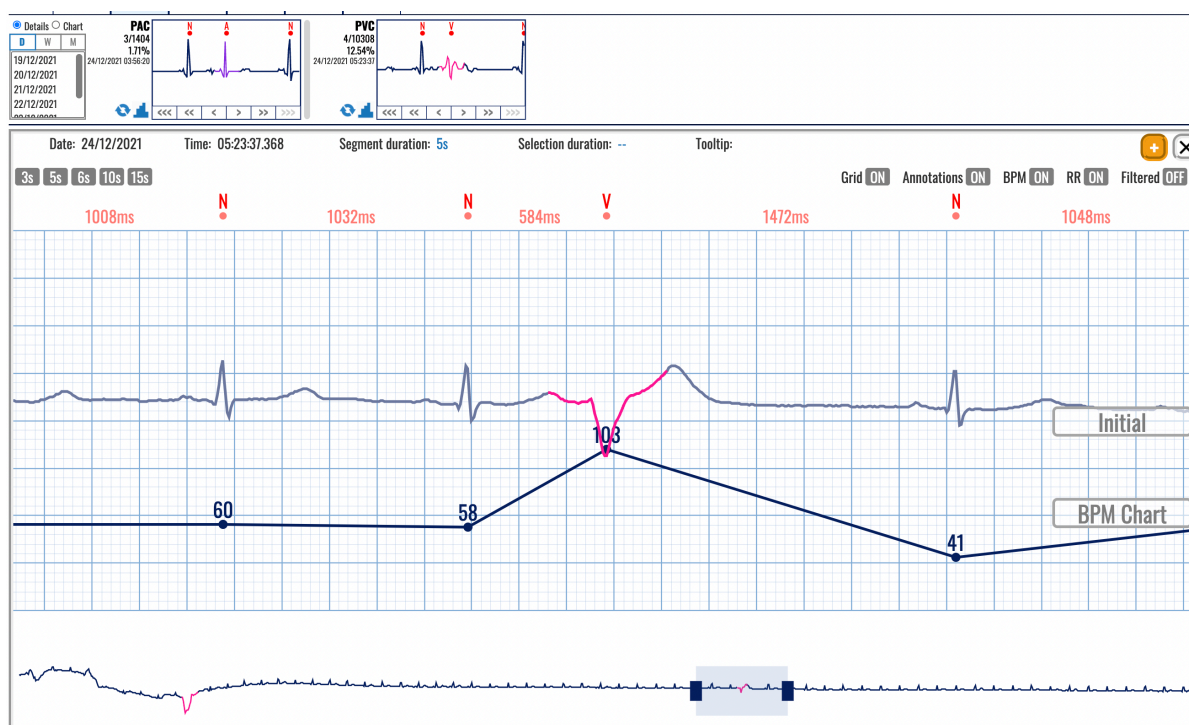


Figure 83: Extended viewer displaying the detected beat type in the beats' navigator.

Right from the information box, there is:

- A display box with an ECG strip presenting the annotated beat type and
- Navigation buttons below the picture containing links:
 - Three left arrows (“<<<”) – displays an ECG recorded the previous day (24 hours prior);
 - Two left arrows (“<<”) – displays an ECG recorded the previous hour (one hour 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 (one hour after) and
 - Three right arrows (“>>>”) – display an ECG recorded the next day (24 hours after).

The display box presents a thumbnail preview with the current annotation beat type located in the middle of the box so you can analyze it in context to the previous and next beats. The beat is colored to correspond to the beat type for easier identification.

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The annotation abbreviation and the annotation display box have tooltip information on the mouse over the full name of the annotation. A navigation button can be inactive if there are no annotated beat types for the navigation criteria.

If the content section width is not sufficient to fit all annotation information boxes, the content section is extended by means of a horizontal slide mechanism.

Histogram of Detected Beat Types

The Beats navigator can present annotated beats histograms (Figure 84). The histogram shows the count of occurrences calculated per hour, so you can easily monitor when these detected beats occurred.

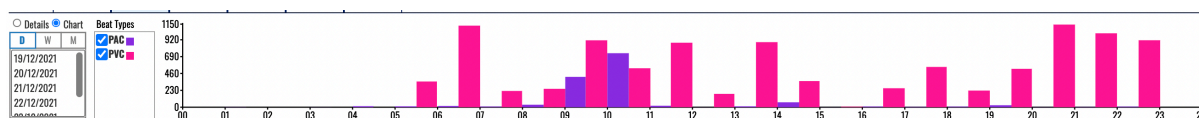


Figure 84: Column bar histogram of annotated beat types in the beats navigator.

A beat type selector (Figure 85) appears on the right from the information domain selector. It contains a list of detected beat types and check boxes next to them to select what will be displayed in the content box. Multiple beat type information can be shown within a single-column chart if more than one beat type is selected. By default, all beat types are chosen.

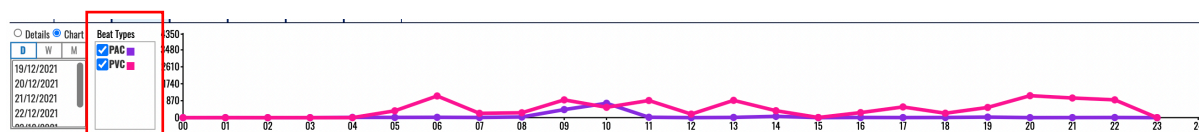


Figure 85: Beat type selector box for line-based histogram of annotated beats in beats navigator.

The histogram is a column view or line-based chart, and each detected beat type is presented with a different color. The scale is displayed on the left side next to the vertical axis, and the presented values are in numbers (occurrences of detected beat type). The horizontal axis features time intervals, while the vertical axis shows the number of occurrences of corresponding beat types in an hour.

The monitoring settings page (invoked by clicking the settings icon in the application header) can be used to set up other views of the histogram, such as a line chart (Figure 85) instead of a column bar chart (Figure 84). You can also choose to present the histogram with relative percentages (Figure 86) instead of absolute values (Figure 84). The monitoring settings section provides details on controls that toggle the histogram formatting.

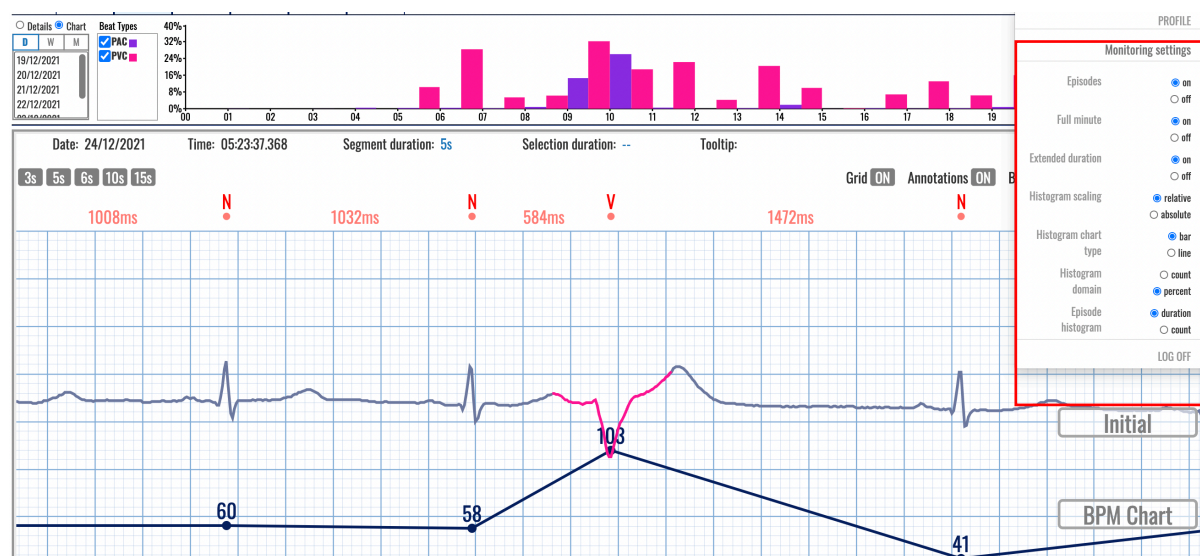


Figure 86: Histogram of detected beat types presented by lines instead of column bars.

5.9. Episodes

The episodes navigator is toggled between bpm, beats, episodes, events, QT, and alerts in the monitoring header section by clicking the toggle switch.

The role of the Episodes (Figure 87) is to provide quick access to information on detected rhythm episodes for a particular period and to navigate through appearances of detected arrhythmia episodes. An additional visualization and monitoring tool is provided for detailed analysis of the detected arrhythmia.

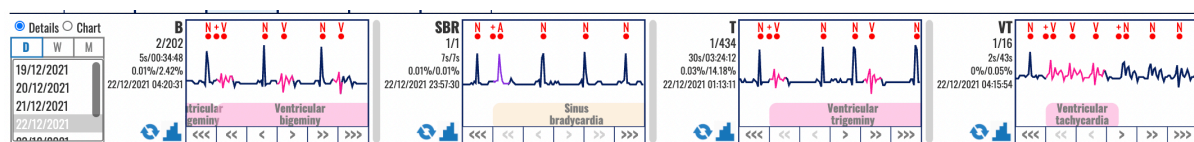


Figure 87: Episodes' navigator displays the detected arrhythmia episodes.

The episode information appears in the same area of the hour selector and ECG strip selector sections combined from the BPM navigator instead of the Beats navigator.

It is divided into two sections:

- Control section – located on the left of the dashboard; contains the controls that determine the content of the content section and
- Content section – located on the right of the dashboard; contains statistics and quick access to the annotations for a selected period and information domain.

The control section (Figure 88 and Figure 79) has one subsection and one radio button group:

- Period selector section (D, W, M) – located on the left side of the control section used to select the period for the content section; and
- Information domain selector (two radio buttons that form a group) – located on the top of the control section and is used to determine whether the content section will contain details about beat annotations or charts about them.

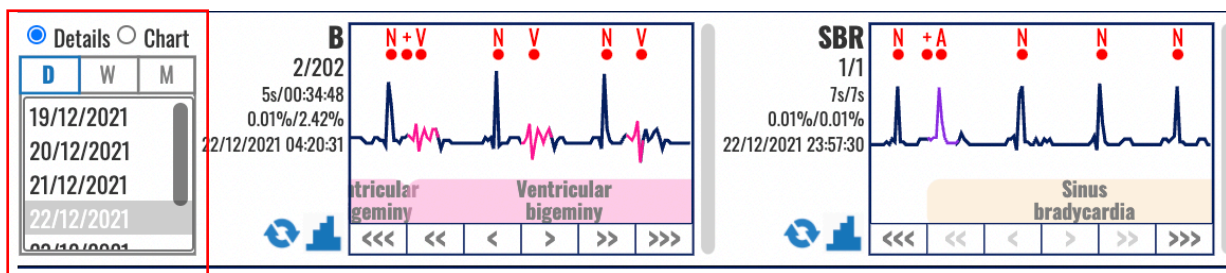


Figure 88: Control section of episodes navigator.

The period selector section (left side in the control section, Figure 88) has a header on the top and a list of date ranges. If there are more dates than those displayed in the list, there is vertical navigation through the list.

The header is made up of a toggle switch with three options:

- Day toggle (D);
- Week toggle (W); and
- Month toggle (M).

Only one toggle option can be active at a time. The summary information presented in the content section corresponds to the period selected by this toggle switch.

The list of dates contains available periods with duration by the active toggle option from the header. Only one list selection can be active at a given time.

The information domain selector has two radio buttons that form a radio button group and display the options: Details and Chart. When the option “Details” is selected the content section of the episodes’ navigator displays the dashboard of rhythm episodes (Figure 89 and Figure 80) and when the option “Chart” is selected the content section presents the histograms of rhythm episodes (Figure 90).

The content section of the episodes, located on the right side of the episode navigator (Figure 89), provides statistical information and quick access to the selected information domain (episode annotations) for a period selected from the episode control panel.

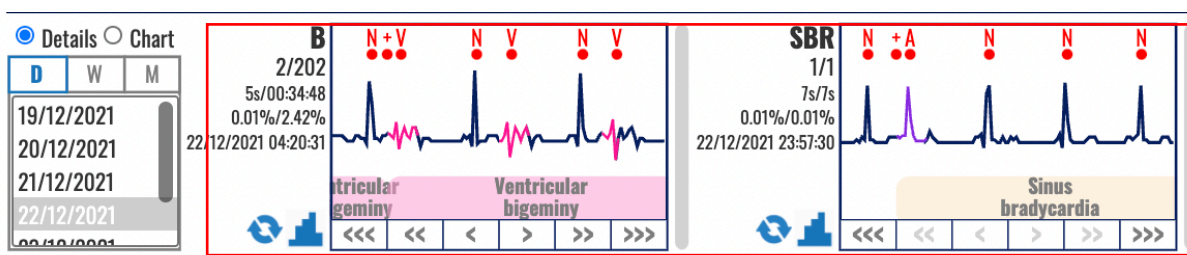


Figure 89: Content section of episodes navigator representing dashboard of annotated episodes.

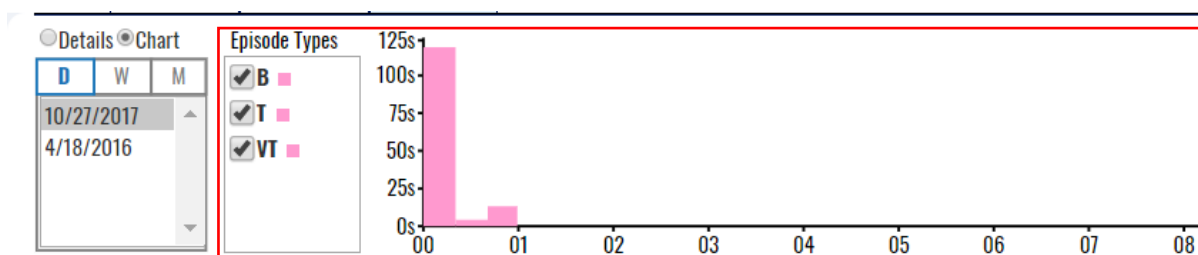


Figure 90: Content section of episodes navigator representing histogram of rhythm episodes.

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Dashboard of Rhythm Episodes

The dashboard can present detected rhythm episodes (Figure 91) by clicking the corresponding radio button.

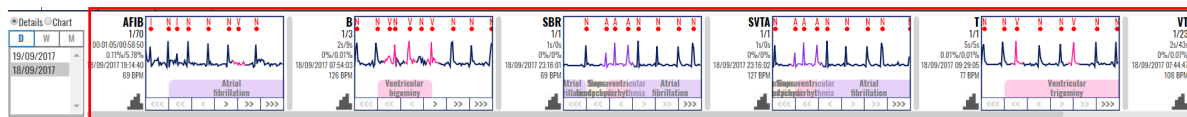


Figure 91: Dashboard of detected rhythm episodes.

When the information domain is set to “Details,” the content section provides an information box for each episode detected in the selected period.

The information box for detected rhythm episodes contains the following:

- An abbreviated name of the episode;
- Current identification and the total number of rhythm episodes (the first number is the current episode identification and the second the total number of episodes);
- Duration of the current episode and total duration of all episodes, along with percentage (relative to the total recording duration in the selected period);
- The date and timestamp of the beginning of the currently displayed rhythm episode,
- The average, minimum, and maximum heart rate of the analyzed episode; and
- The column chart icon is a shortcut to the corresponding episode histogram column chart (a shortcut for switching to the episode histogram context of the content section).

A click on the displayed boxes that represent the detected beats will open the extended viewer (Figure 92) to enable a better representation of the detected arrhythmia.

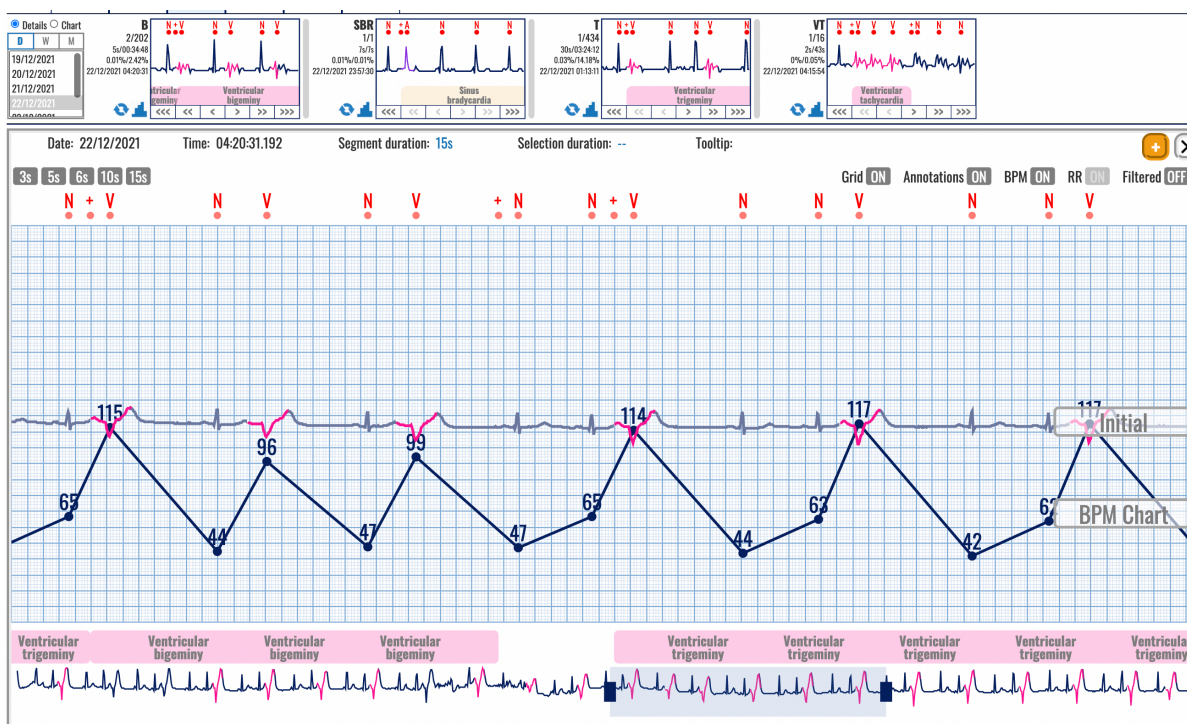


Figure 92: Detected rhythm episodes displayed in the extended viewer.

Right from the information box, there is:

- A display box with an ECG strip presenting the analyzed episode and

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- Navigation buttons below the picture containing links:
 - Three left arrows (“<<<”) – display an ECG recorded the previous day (24 hours prior);
 - Two left arrows (“<<”) – display an ECG recorded the previous hour (one hour prior);
 - One left arrow (“<”)– displays the previous recorded ECG (30 sec prior);
 - One right arrow (“>”) – displays the following recorded ECG (after 30 seconds);
 - Two right arrows (“>>”) – display an ECG recorded the following hour (one hour after) and
 - Three right arrows (“>>>”) – display an ECG recorded the following day (24h after).

The episode display box gives a thumbnail preview of the current episode. When you mouse over the episode abbreviation on the left side of the information box, a tooltip appears that displays the full name of that episode.

A navigation button can be inactive if such an episode does not exist.

If the content section width is not sufficient to fit all episode information boxes, the content section is extended by means of a vertical slide mechanism.

Histogram of Rhythm Episodes

The dashboard can display a histogram of detected rhythm episodes (Figure 93) by clicking the “Chart” radio button from the information domain selector.



Figure 93: Histogram of detected rhythm episodes.

By default, the episode histogram is displayed in a bar-column view. Figure 93 presents a line-based histogram selected by the settings option.

The x-axis features time intervals, while the y-axis features the number of episodes per interval. There is a control that acts as a series selector so that multiple annotation information can be shown within a single-column chart. The series values can represent the number of episodes in the period or their percentage relative to the sum of all R waves. The chart type can be either a bar chart or a line chart. The series numbers can be either in count or percent. The information domain can either relate to the episode number or episode duration. The controls that toggle the histogram formatting can be found in the monitoring settings section.

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5.10. Events

The events navigator is toggled between bpm, beats, episodes, events, QT, and alerts in the monitoring header section by clicking the toggle switch.

The EVENTS section is shown when the tab pill “EVENTS” is selected from the monitoring header menu. The event information appears in the same area of the hour selector and ECG strip selector sections combined from the BPM navigator instead of the Beats or Episodes navigator. Whereas the Beats and Episodes sections used grouping by type, the Events dashboard does the grouping by the feeling and activity information provided with each recorded event.

The region is divided into two sections:

- Control section – located on the left of the dashboard; contains the controls that determine the content of the content section;
- Content section – located on the right of the dashboard; contains additional information and quick access to the events for a selected period;

The control section has one subsection:

- Period selector section (D, W, M) – located on the left side of the control section used to select the period for the content section;

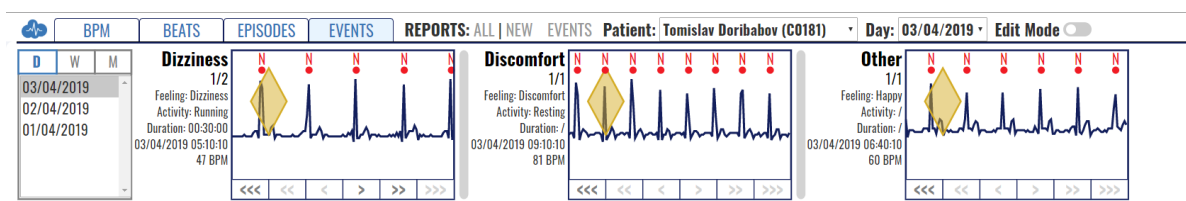


Figure 94: Content section of events navigator.

Period selector

This section shows a rectangle on the left with one button group. The button group, consisting of buttons “D,” “W,” and “M,” allows the user to select a specific day, week, or month for the selected patient and generate the results for that period. Unlike the beats and episodes sections, this section does not have radio buttons to choose between detailed or chart view but rather detailed view only.

The period selector section (left side in control) has a header on top and a list of date ranges. If there are more dates than those displayed in the list, then there is a vertical navigation through the list.

The header is made up of a toggle switch with three options:

- Day toggle (D);
- Week toggle (W);
- Month toggle (M);

Only one toggle option can be active at a time. The summary information presented in the content section corresponds to the period selected by this toggle switch.

The list of dates contains available periods with duration by the active toggle option from the header. Only one list selection can be active at a given time. Therefore, the content section only has dashboard information on the events.

The content section of the events, located on the right side of the events’ navigator, provides additional information and quick access to the selected information domain (event domain) for a time period selected from the events’ control panel.

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Dashboard of Events

The content section shows boxes of ECG signals of the events recorded in the processed recordings; the user can see where these events were recorded by looking at the signal. The grouping is done by conjoining the different feelings and activities, called 'categories.' The feelings can be set to one predefined: palpitations, dizziness, and discomfort. They can be custom or undefined. The activity can be set to one of the three predefined: resting, active, sports, custom, or undefined. The event duration can be set to a duration value or be undefined. It also shows some additional data on the left of the boxes: The event category, the feeling during the event, the activity during the event, the duration of the event, the time of the event start, and the BPM during the event.

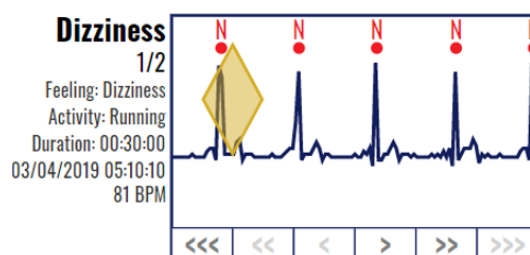


Figure 95: Dashboard of event.

For each event category box, the doctor can navigate through the events using the navigation arrows on the bottom part of the box (<<<, <<, <, >, >> and >>>).

The information box for recorded events contains the following:

- event category,
- current identification and the total number of event instances per category (the first number is the current event identification number, and the second is the total number of events per category),
- the feeling during the event,
- the activity during the event,
- the duration of the event,
- timestamp of the event start and
- average bpm value during the event.

Right from the information box, there is:

- A display box with an ECG strip presenting the current event and
- Navigation buttons below the signal display containing links:
 - <<< the first event in the previous day (if there is such a record),
 - << the first event in the analyzed period,
 - < the previous event in the analyzed period,
 - > the following event in the analyzed period,
 - >> the last event in the analyzed period and
 - >>> the last event on the next day (if there is such a record).

The event display box gives a thumbnail preview of the current event. If such an event does not exist, a navigation button can be inactive. If the content section width is not sufficient to fit all event information boxes, the content section is extended by means of a vertical slide mechanism.

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5.11. QT Interval

The QT interval TAB is one of the options in the list of TABs (BPM, BEATS, EPISODES, EVENTS, QT, and ALERTS) in the monitoring header section. Clicking the QT TAB displays a new interface (Figure 96).

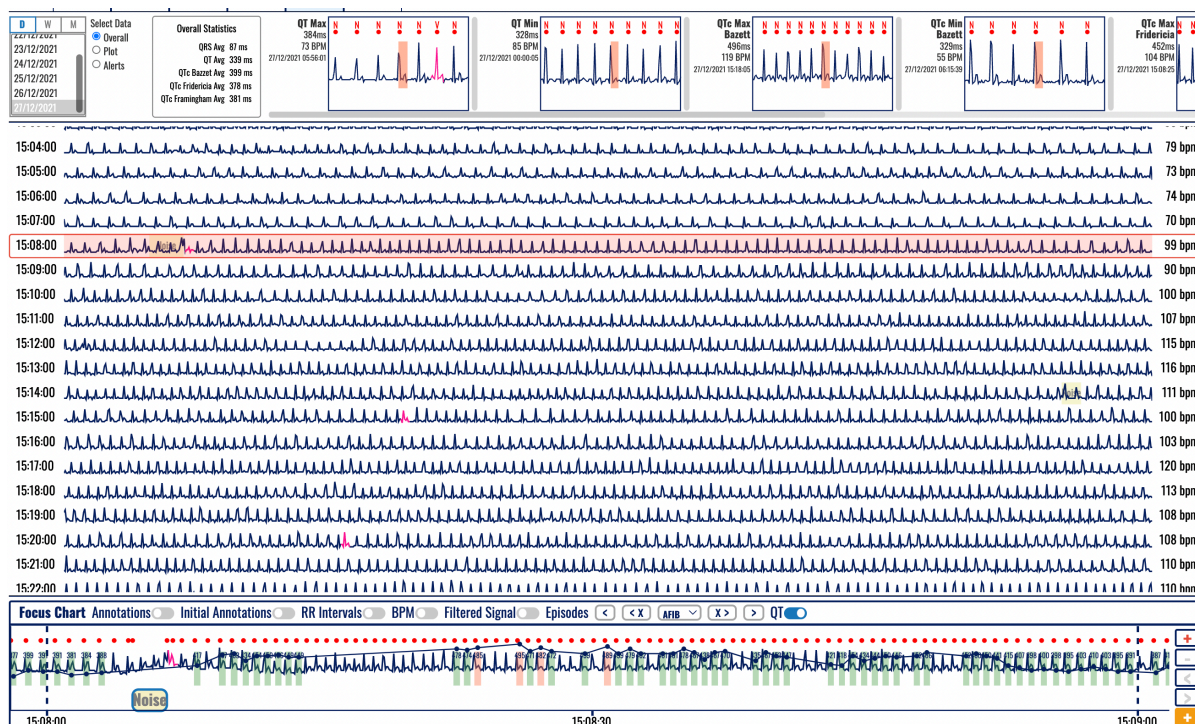


Figure 96: Overall extreme values presented in the QT TAB.

The QT information appears below the header section (where the daily and hour selectors are presented for the BPM TAB}.

The region is divided into two sections:

- Control section (Figure 97) – located on the left of the dashboard; contains the controls which determine the content of the content section;
- Content section – located on the right of the dashboard; contains additional information and quick access to the events for a selected period;

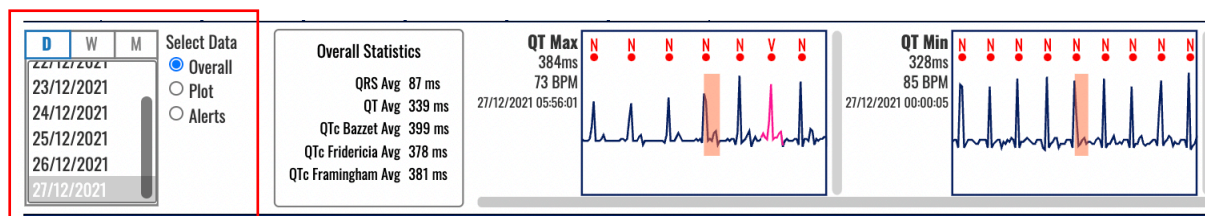


Figure 97: Control section of the QT TAB.

The control section (Figure 97) has one subsection and one radio button group:

- Period selector section (D, W, M) – located on the left side of the control section used to select the period for the content section; and
- The data domain selector with three radio buttons (Figure 98) is located on the right side of the control section and determines whether the content section will contain details (dashboard) about the Overall, Plot or Alerts as Selected Data.

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The content section is displayed right from the Control section (Figure 98).

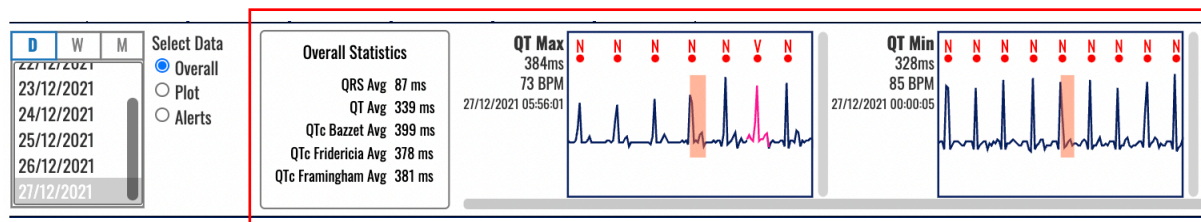


Figure 98: Content section displaying the Overall dashboard of the QT TAB.

Overall Dashboard

When Overall is selected from the Select Data radio button group (default option), as presented in Figure 96, the content section is divided into two segments:

- Overall statistics table that contains the following values:
 - QRS Avg (ms)
 - QT Avg (ms)
 - QTc Avg (ms) according to the according to the Bazett formula,
 - QTc Avg (ms) according to the Fridericia formula, and
 - QTc Avg (ms) according to the Framingham formula.
- QT/QTc Min and Max values, which can be the total of the following eight:
 - QT Max and QT Min,
 - QTc Max and QTc Min, according to the Bazett formula,
 - QTc Max and QTc Min according to the Fridericia formula, and
 - QTc Max and QTc Min according to the Framingham formula.

Clicking displayed boxes for detected QT/QTc Min/Max segments will open the extended viewer instead of a list of ECG strips. This provides a detailed overview and representation of the detected QT interval.

The following information is available for each detected QT interval:

- The length of the interval expressed in ms,
- BPM value on the selected RR interval between the beginning of the QT interval and the next beat
- Timestamp when the QRS was detected

Both long and short QT interval values are displayed in Figure 99. The slider below the displayed boxes of found extreme values may slide to the right to present those that might not appear in the window. For example, the Framingham and Fridericia extreme values are displayed in Figure 100.

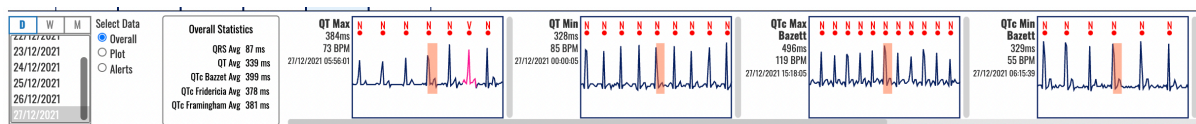


Figure 99: Long and short measured QT and QTc intervals calculated according to Bazett formula.

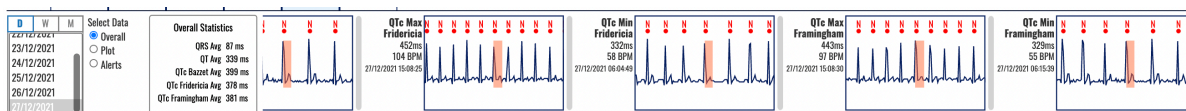


Figure 100: Long and short QTc intervals calculated according to Framingham and Fridericia formulas.

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Clicking on a selected box will open the extended viewer. For example, Figure 101 presents the extended viewer for the selected QTc min according to the Bazett formula.

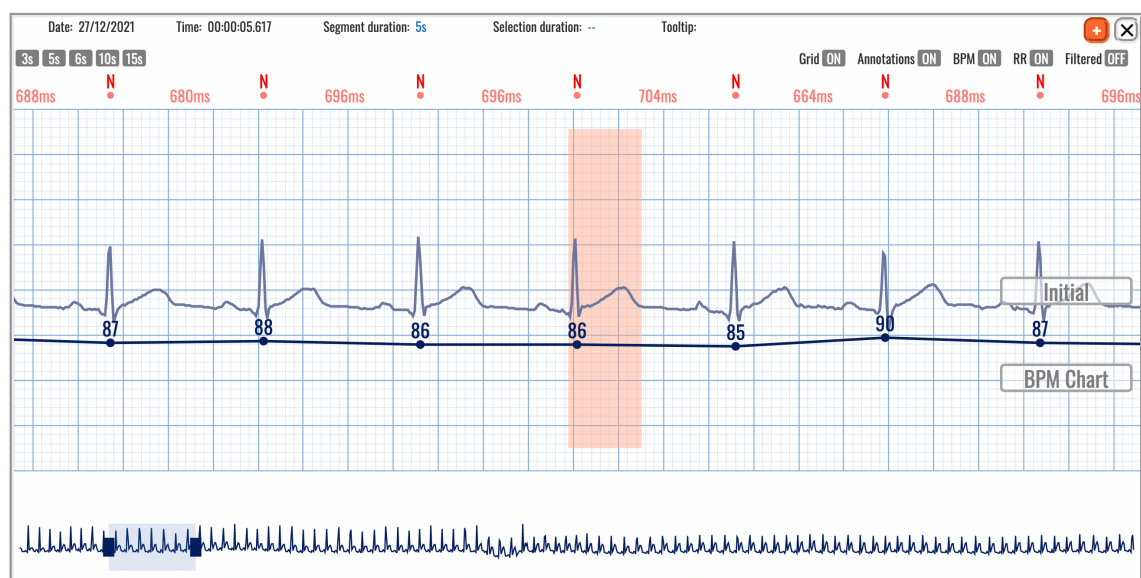


Figure 101: Extended viewer displaying the QTc min according to the Bazett formula.

The extended viewer presents information on the top row and a set of toggle buttons (Figure 102) to activate the Grid, annotations, information about heart rate (BPM), RR interval in ms, and presentation of the filtered signal.



Figure 102: Toggle buttons for better visualization.

An example of presenting the filtered signal is presented in Figure 103.

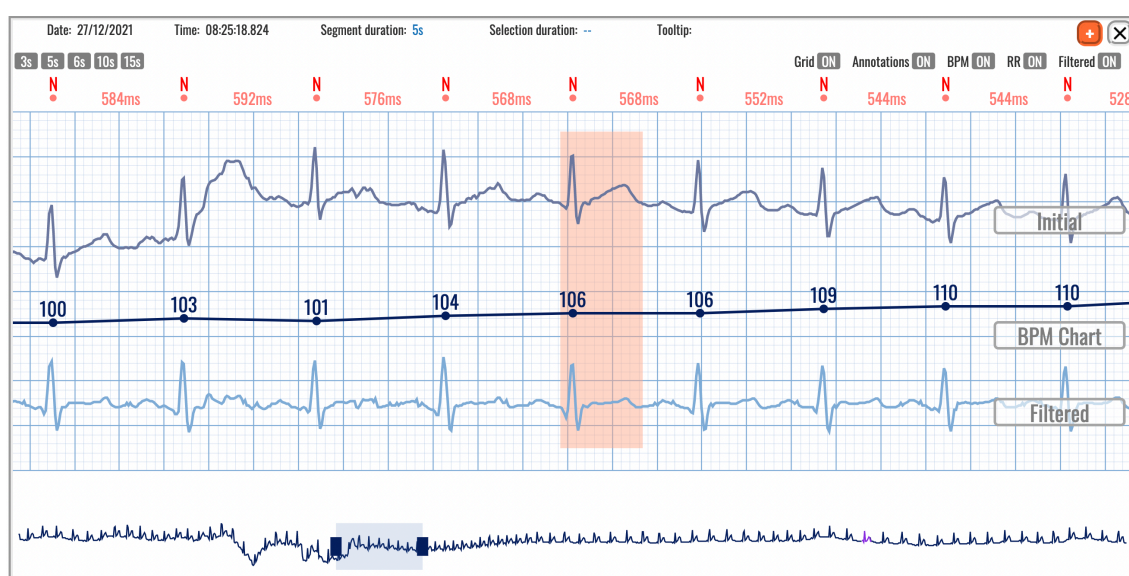


Figure 103: The extended viewer displays the QT interval on the filtered (below) and the ECG (above) signal.

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Clicking on the plus sign with an orange background will add the selected ECG strip and marked QT interval to the report. An information box confirms if the addition is successful (Figure 104).

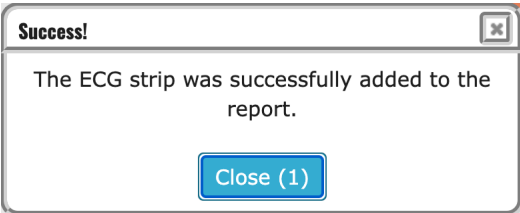


Figure 104: An information window is displayed after adding an ECG strip with a QT interval to the report.

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Plot's Dashboard

The plot dashboard (Figure 105) opens by selecting the Plot option in the radio buttons. The upper part contains the same control section as in the Overall dashboard. A group of radio buttons is shown in the lower part to switch between QTc calculations according to the formulas:

- Bazett,
- Fridericia, and
- Framingham.

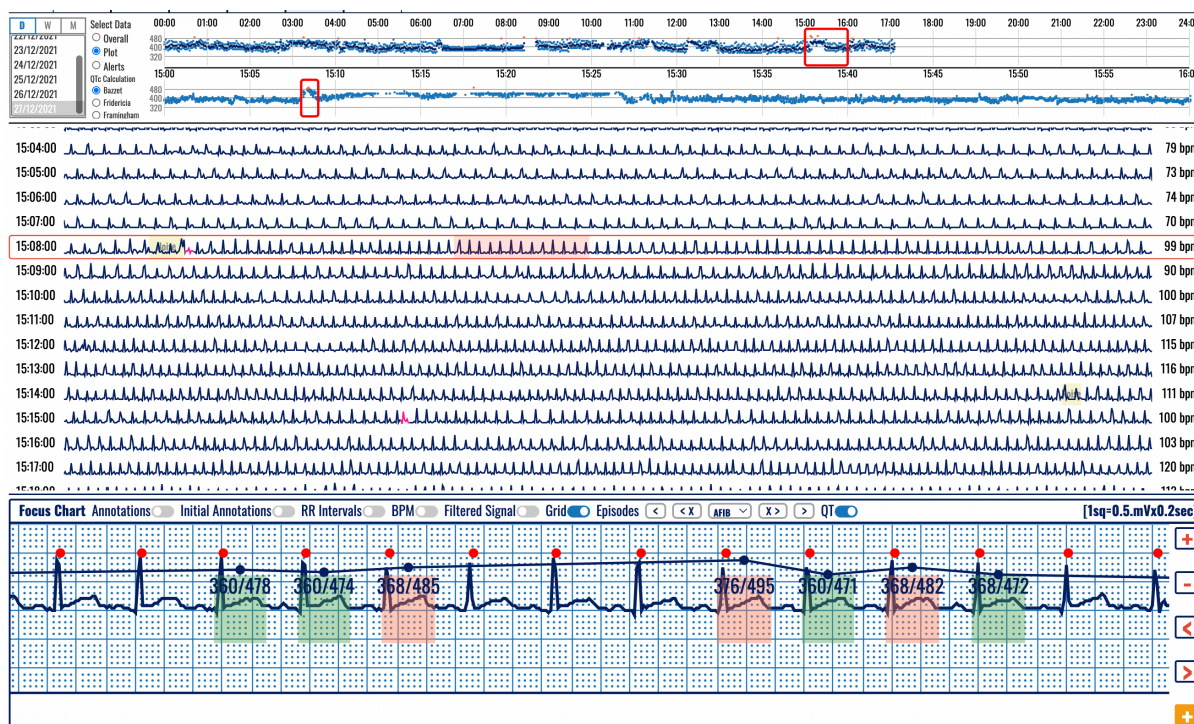


Figure 105: Plot navigation over ECG strips displaying the QT intervals.

The content section (Figure 106) contains a presentation of the time series:

- A daily navigator (24-hour plot) that shows one preselected hour is chosen by default based on data availability. This plot is clickable, and an hour can be selected to be presented in the hourly navigator.
- An hourly navigator (second plot) shows the selected QTc calculation, which can be according to the formulas introduced by Bazett, Fridericia, or Framingham. This plot is clickable and is used to select an ECG strip to be presented in the main window.

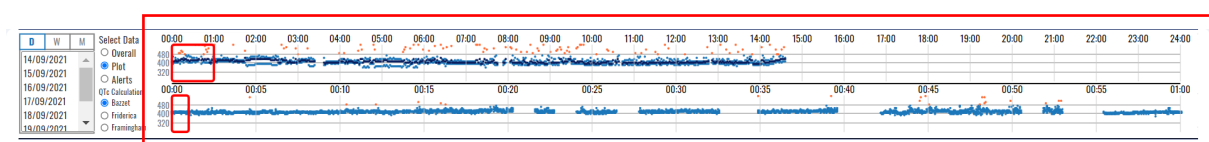


Figure 106: Daily and hourly navigators in the plot dashboard of detected QT intervals.

Both plots contain different color dots, which can be:

- Orange – if the QTc value is above 480 ms or below 320
- Dark blue – average value
- Light blue – minimum and maximum values

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Values above 560 ms and below 240 ms are shown on the upper/lower border accordingly.

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Alerts Dashboard

The Alerts dashboard (Figure 107) opens by selecting the Alert option in the radio buttons. It contains the same control section as in the Overall dashboard.

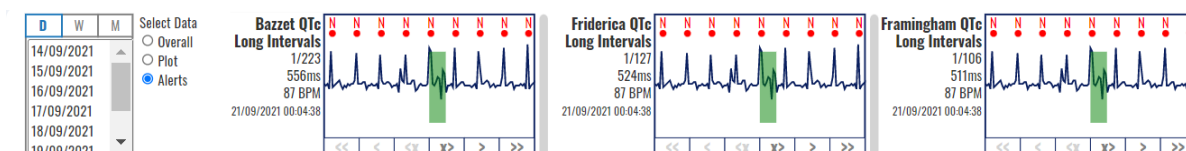


Figure 107: Alerts dashboard.

The content section provides visualization of short and long QTc values and can be up to a total of six visualizations:

- Bazett QTc Long and Short Intervals,
- Fridericia QTc Long and Short Intervals, and
- Framingham QTc Long and Short Intervals.

A click on the corresponding box will open an extended viewer and display the first appearance of the ST segment. For example, Figure 108 presents a long QTc interval calculated according to the Bazett formula, and Figure 111 shows a short QTc interval calculated according to the Fridericia formula.

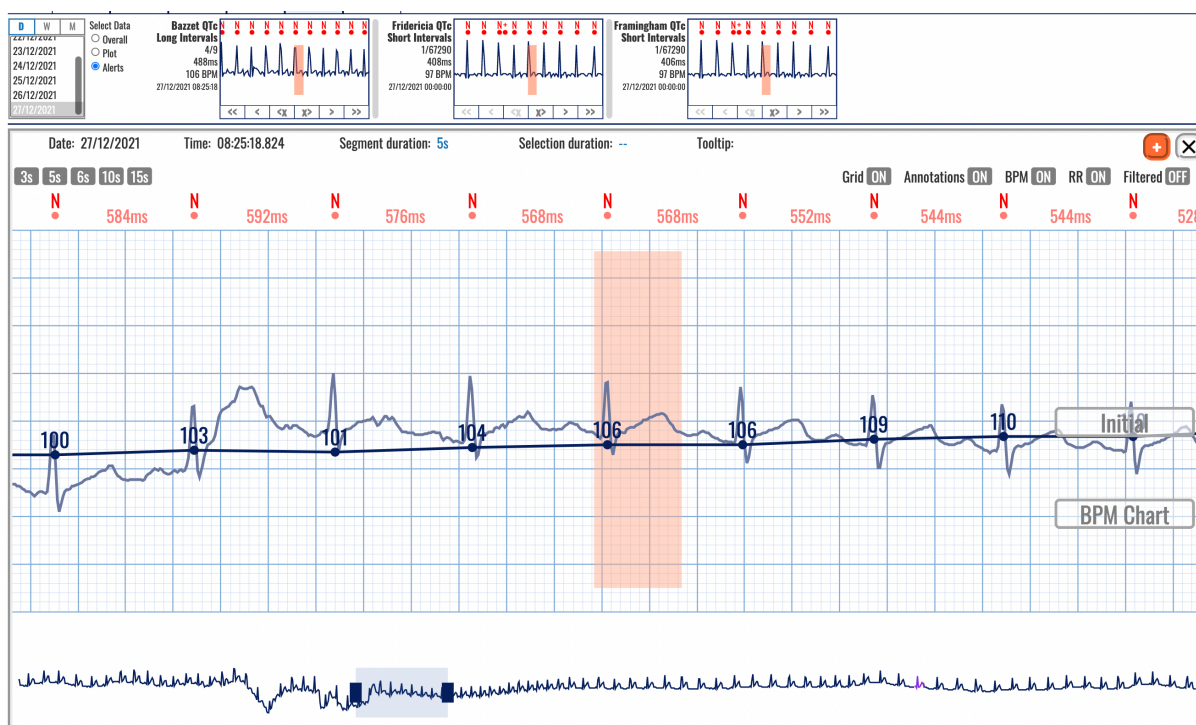


Figure 108: Long QTc interval according to the Bazett formula.

These boxes allow easy navigation through the long or short QTc intervals list. Six navigation boxes are available (Figure 110), and four of them are the ordinary navigation buttons: (>) next in the list, (>>) last in the selected day, (<) previous in the list, and (<<) first in the selected day.

Note that the noise may corrupt the ECG signal and initiate the wrong measurement of the QT interval, as presented in Figure 109.

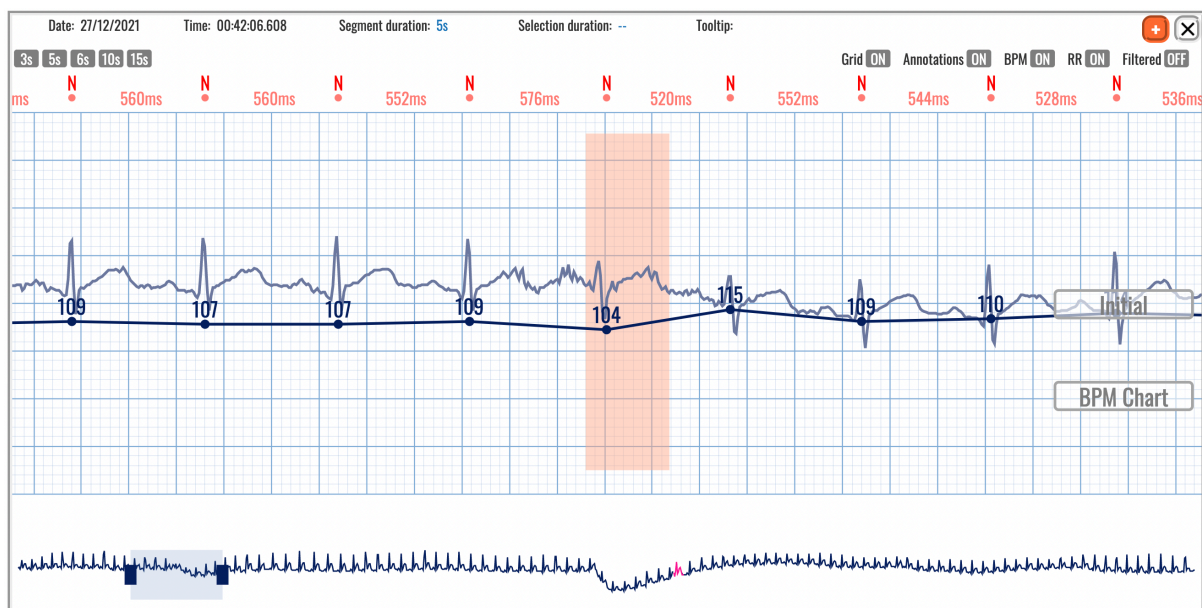


Figure 109: Noise may corrupt proper detection of the QT interval.

Therefore, besides the navigation buttons (Figure 110), there are two buttons to delete and navigate through the list (X>), meaning it will delete the current selected QT interval (if the doctor decides that it was wrong due to noise corrupted signal) and move to the next in the list. In contrast (<X) will delete the current selected QT interval and move to the previous in the list.

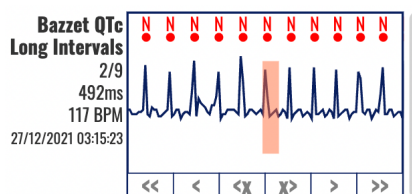


Figure 110: Buttons for deleting and navigation of long QTc intervals according to the Bazett formula.

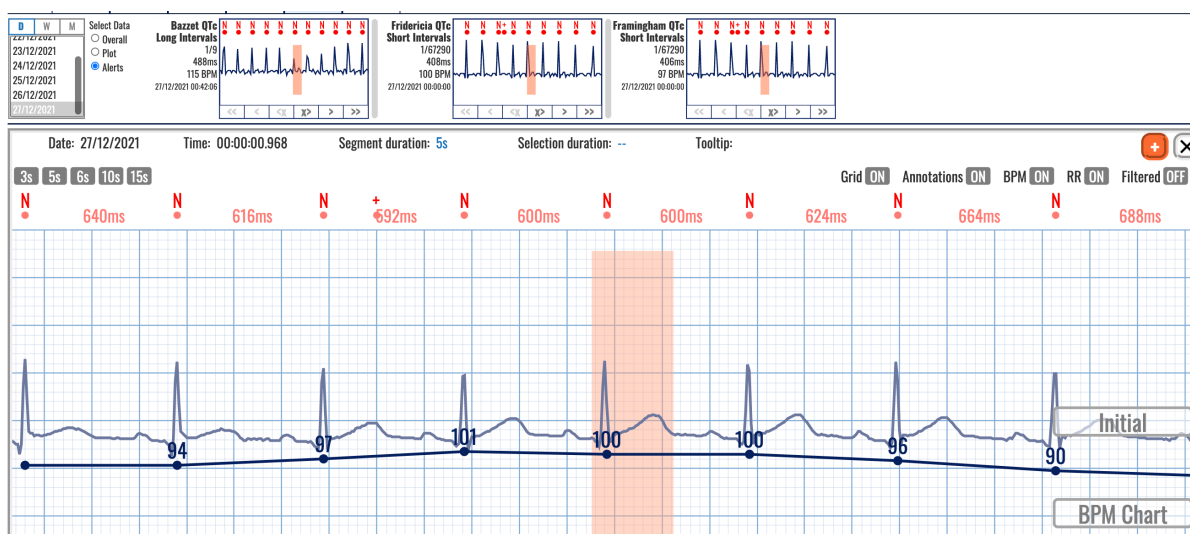


Figure 111: Selected short QTc interval according to the Fridericia formula in the Alarms section.

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5.12. Alerts

The Alerts TAB is one of the options in the monitoring header section of the list of TABs (BPM, BEATS, EPISODES, EVENTS, QT, and ALERTS). Clicking the ALERTS TAB displays a new interface (Figure 113 and Figure 96). The upper part contains the control and content sections (Figure 112).

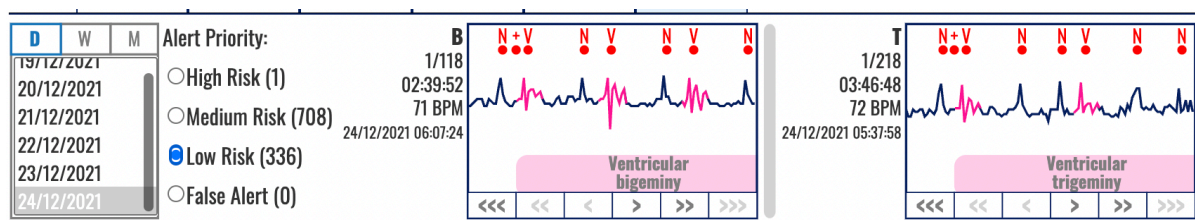


Figure 112: Control and content sections of the Alert TAB.

The control section uses the date selector with three options to select the day (D), week (W), or month (M) and a navigation list to select a particular day. Right of this date selector is a group of radio buttons that allows you to choose the risk level for the defined alerts. Figure 112 shows one occurrence of high risk, 708 occurrences of medium risk, and 336 occurrences of low risk.

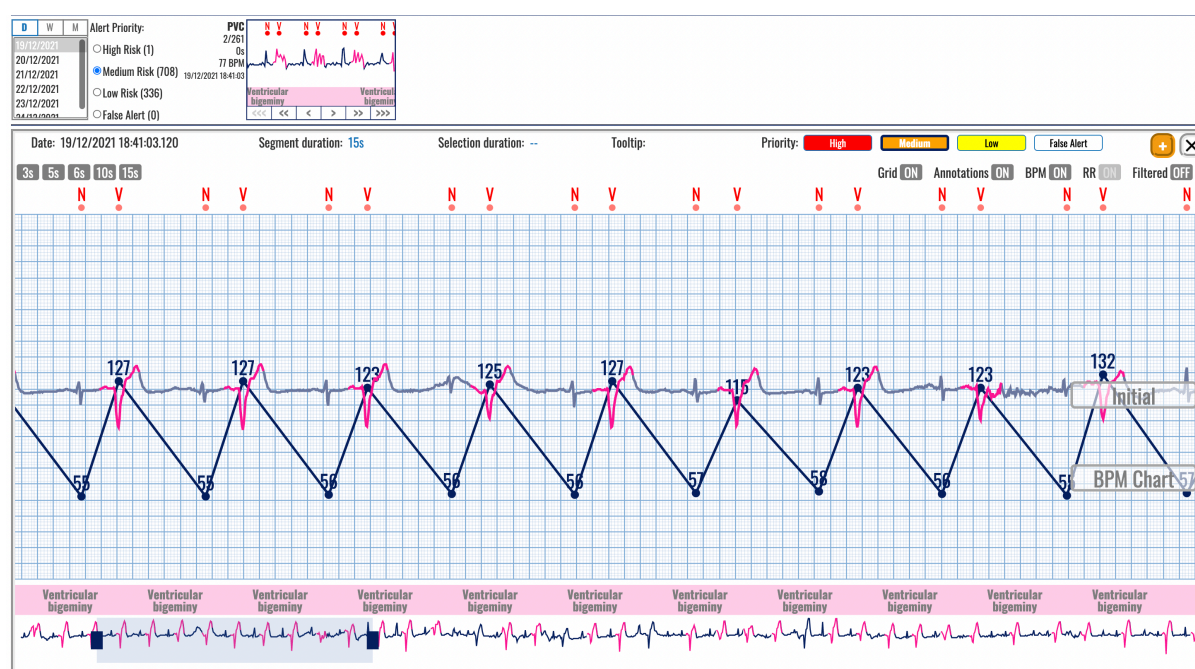


Figure 113: Selected medium-risk alerts.

A click in the boxes of detected alerts will open the extended viewer and present details. For example, medium risk alert (as several PVC per minute over a threshold) is presented in Figure 113, and low risk (Ventricular trigeminy duration over a threshold) in Figure 114.

The thresholds for each patient can be defined as elaborated in Section 4.4 Thresholds.

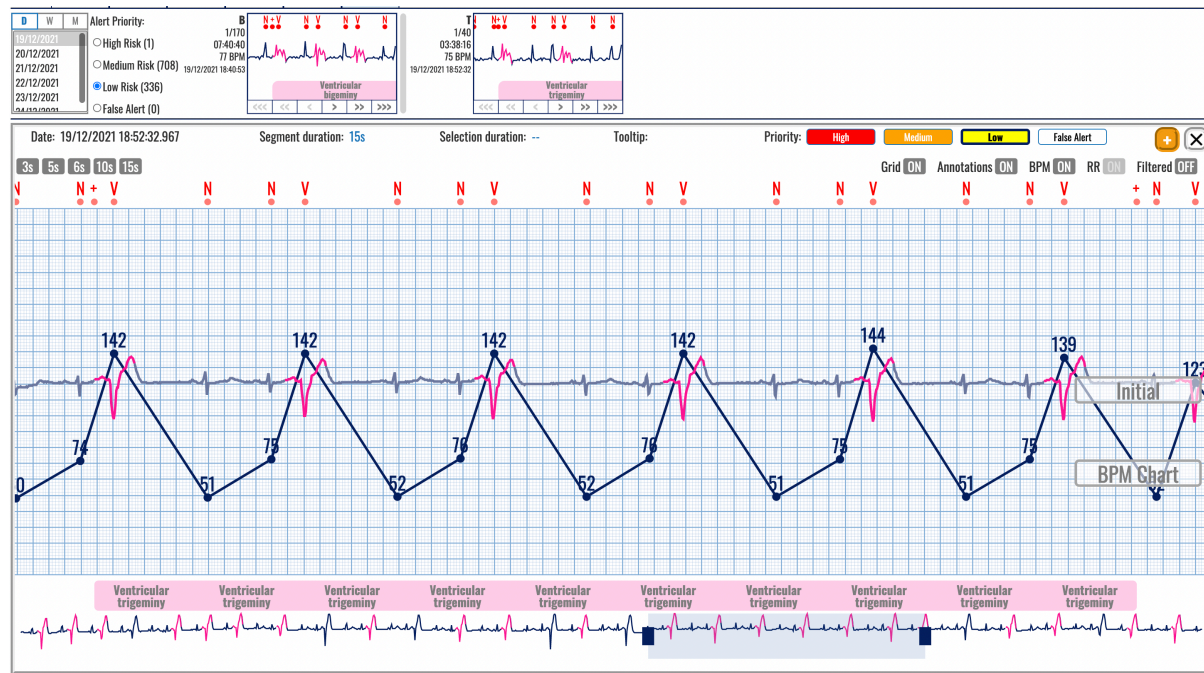


Figure 114: Selected low-risk alerts.

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5.13. Extended Viewer

An extended viewer (Figure 115) can be displayed by clicking on a display box in any of the TABS in the header, such as the annotated beats or detected rhythm episodes, when beats or episode information is analyzed.

The visualization display box from the content section acts as a link to an ECG strip. Upon clicking, the list of ECG strips and the focus chart in the monitoring are replaced by the extended viewer window. The duration of the displayed ECG strip matches the selection; for example, 5 seconds are displayed for a beat type or 10 seconds for a rhythm episode.

The extended viewer window, in addition to containing the ECG signal visualization window, has a header on its own. The header has a timestamp of the annotation, which is displayed in the middle, selection duration information (if any), segment duration information, tooltip information, a group of buttons to determine the detection type, a button to add to the report, and a button to close the window of the extended viewer.

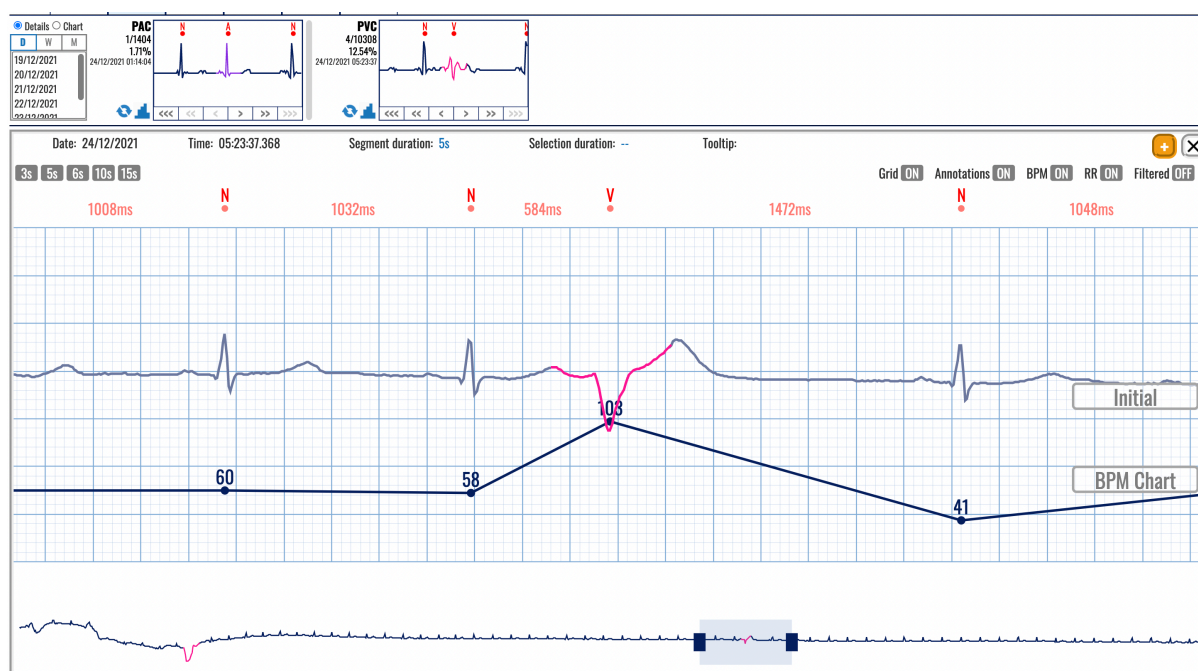


Figure 115: Extended viewer of annotated beats.

The navigation buttons in the displayed box in the header section of the dashboard act as traversal tools for the pop-up window content.

An “add to report” button (Figure 116) will add a 7.5-second ECG strip to the pool of user-predefined ECG strips for report generation. The center point of the 7.5-second ECG strip is the center point of the visible part of the ECG strip from the signal visualization pop-up window.



Figure 116: Tools in the header of the extended viewer and the "Add to report" button.

The toggle switches (Figure 116) will display the grid, annotations, heart rate, RR intervals, and filtered signal.

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A click on the rhythm episode name will open a popup window (Figure 117) to edit the rhythm episode. The episode start and end times are editable and can be changed.

Clicking on an appropriate button that represents another arrhythmia or identification of noise can select another episode.

The Update button will be activated after the selection, enabling you to click on and confirm the change. Click on the Cancel button will return without any change in the editing.



Figure 117: Popup window to edit a rhythm episode.

The Delete button will delete the selected rhythm episode. A confirmation window (Figure 118) will appear with two options to confirm (Delete button) and cancel the deleting.

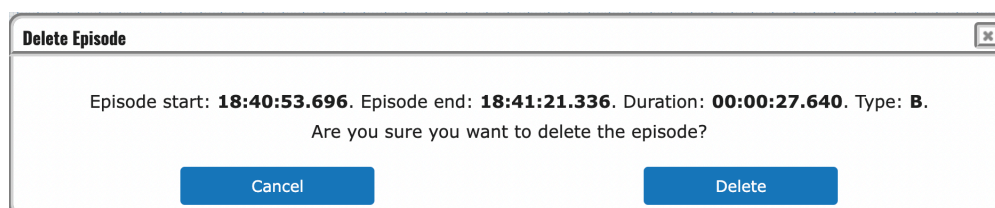


Figure 118: Dialog window to confirm deleting the rhythm episode.

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5.14. Advanced Features

Redo/undo Operations

The changes to beat annotations and episodes have versioning control, meaning the user can undo and redo actions to the changes made. The undo action is done by simultaneous press of the Ctl + Z button combo, while the redo action is done by simultaneous press of the Ctl + Y button combo.

Query String

When the user navigates through the ECG recordings on the monitoring page, the query string in the web page address bar is simultaneously updated. Consequently, if the user reloads the page, on page load, the positioning of the monitoring page will be the same, timewise and magnification-wise. In addition, this feature enables easier sharing of the monitoring page content by copy-pasting the entire address string of the monitoring page.

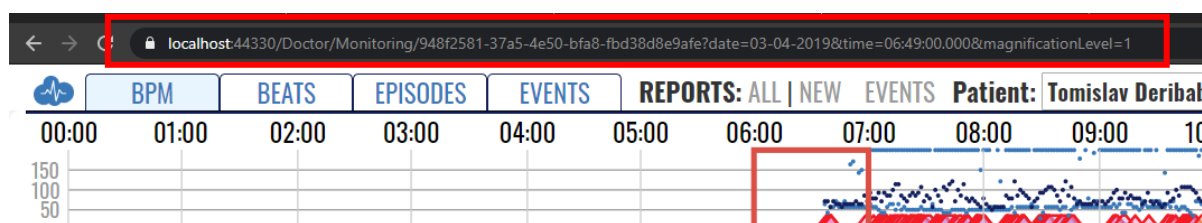


Figure 119: Query string

Beat Order Number Navigation

The user can navigate to a specific beat in the current day's data, order-wise. The user presses the Ctrl + F button combination to access this functionality and enters the beat order number N in the pop-up window. Right after, the monitoring page navigates directly to the Nth beat. This function is used for research and testing purposes, but it is also available to all users with access to the monitoring page.

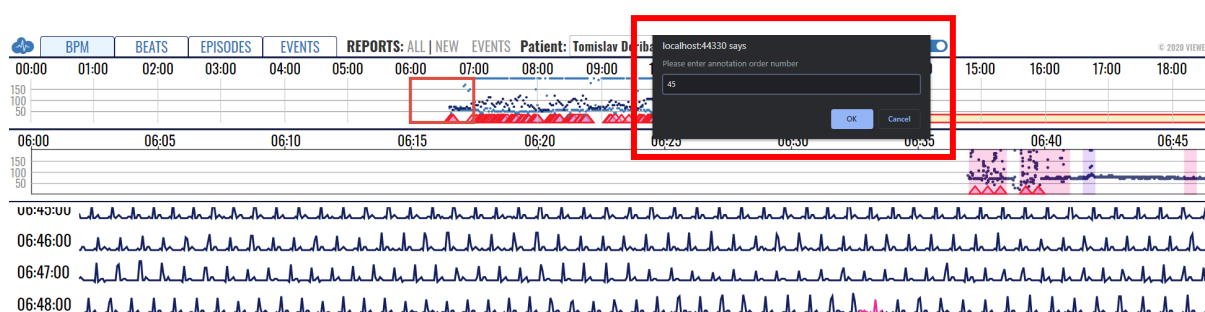


Figure 120: Navigation to specific beat order number

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6. How to Create and Edit a Report

6.1. Create a Report

Access the Report



Figure 121: Monitoring page header.

A report is created by clicking the “NEW” text link in the monitoring page header (Figure 121). After accessing the report creation page, the doctor can adjust the measurement period and set preferred information.

Report Header

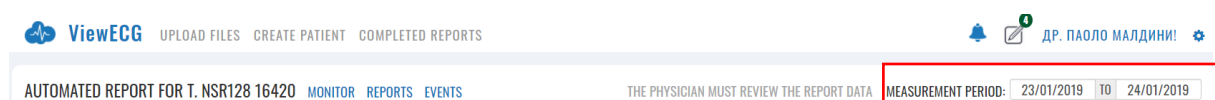


Figure 122: Report header.

The standard application header is above the custom report header (Figure 122). In the custom report creation page header, the patient's full name is placed on the far left side. Next to the patient name, there is a quick access section with links to the monitoring, reports, and events index pages. On the right, a measurement period is denoted.

Measurement Period

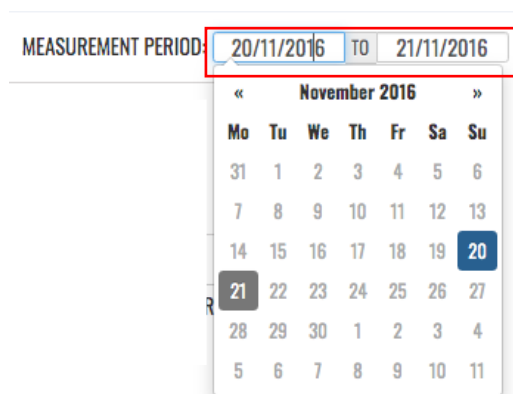


Figure 123: Measurement period selection.

The monitoring period section (Figure 123) consists of two date-picker controls that determine the start and end of the period for which the report is generated. The default values of the date-picker controls are set to the last recording date, lasting for the entire recording session. In the example in Figure 123, the period is set for a two-day recording session but can be edited to a single-day recording if needed.

If the patient's measurements are only for one day, the report date will be hard coded on the upper right side of the report header, and the user cannot change it (Figure 124).

Figure 124: Single day measurement.

In case there are ECG strips added for the report that predates one week before the last recording date, the default period for the report will be set with a start date matching the oldest ECG strip and an end date that is greater than the start date for one week; In case the time interval between the oldest and newest ECG strips is more than a week apart, the report period will match the period between the oldest and newest ECG strips; The granularity of the reporting period requires that the whole-day findings be included in the report summary information; for example, we cannot exclude the findings before 13:00:00 if we want to include them after 13:00:00. A maximum of 30 days can be included in the report summary information.

MEASUREMENT PERIOD: 20/11/2016 TO 21/11/2016

November 2016						
Mo	Tu	We	Th	Fr	Sa	Su
31	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	1	2	3	4
5	6	7	8	9	10	11

Figure 125: Data selector for the report.

The date picker controls can only select days when measurements were taken. They limit the availability of selectable dates in accordance with the dates for which measurements are present. After a selection from the date picker controls is made, i.e., the measurement period is changed, the page is reloaded, and it features information on the newly selected measurement period.

Patient Details

Patient Details

Patient Mark Shield
Sex Male
Address 588 Hoffman Avenue

Age 69
Height 180 cm
Weight 50 kg

Pacemaker No
Medications
Indications

Figure 126: Patient details section.

The patient details sections (Figure 126) feature the following information on the patient:
Patient – the patient's full name;

- Sex – the gender of the patient;
- Address - the patient's address;
- Age – the age of the patient;
- Pacemaker – indicates whether the patient is using a pacemaker device;
- Weight – the weight of the patient;
- Height – the height of the patient;

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- Medications - the medications the patient was taking during the measurement period and
- Indications – Deviations the patient is prone to, genetic predispositions for certain diseases, medical history and other relevant data to the ECG findings.

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6.2. Summary Information

The summary section (Figure 127) is divided into eight mandatory subsections:

- General information;
- Heart rate;
- Pauses and aberrant beats;
- HRV - Time Domain;
- HRV – Frequency Domain;
- HRV – Other;
- Ventricular Ectopies;
- Supraventricular Ectopies; and
- Other.

Summary Information

GENERAL INFORMATION		HEART RATE		PAUSES AND ABERRANT BEATS	
Analyzed Beats	2753	Min HR-4	80 BPM at 27.10.2017 00:13:55	SA Total	0
Total Recording Duration	00:28:51	Max HR-4	153 BPM at 27.10.2017 00:13:54	Maximum SA	/
Normal Sinus Rhythm Duration	(98.56 %) 00:28:26	Average HR-24 Hours	95 BPM	Micro SA Total	0
ECG Monitoring Start	27.10.2017 00:00:00	Min HR-Hourly	95 BPM at 27.10.2017 00:00:00	Total Aberrant Beats/Runs	0
ECG Monitoring End	27.10.2017 00:29:00	Max HR-Hourly	95 BPM at 27.10.2017 00:00:00		
HRV - TIME DOMAIN		HRV - FREQUENCY DOMAIN		HRV - OTHER	
SDNN	17 ms	ULF	33 ms ² peak at 0.000 Hz	Poincaré SD1	18.96 ms
ASDNN	2 ms	VLF	56 ms ² peak at 0.002 Hz	Poincaré SD2	37.15 ms
SDANN	7 ms	LF	10 ms ² peak at 0.045 Hz	Poincaré SD1/SD2	0.51
NN50	4 / 2690	HF	66 ms ² peak at 0.159 Hz	DFA α1	0.33
pNN50	0 %	HF/LF	0.156	DFA α2	1
rMSSD	17 ms				
VENTRICULAR ECTOPIES		SUPRAVENTRICULAR ECTOPIES		SUPRAVENTRICULAR TACHYARRHYTHMIA	
VE Total	3	SVE Total	0	Number of episodes	1
VE-Pair Total	0	SVE Pair Total	0	Total duration	24s (1.39 %)
Short V-Runs (3≤n<6)	0	Short SV-Runs (3≤n<6)	0	Longest duration	24.9s at 27.10.2017 00:13:31
Long V-Run Total (n≥6)	0	Long SV-Run Total (n≥6)	0	Min HR	63 BPM at 27.10.2017 00:13:56
Longest V-Run	/	Longest SV-Run	/	Max HR	160 BPM at 27.10.2017 00:13:55
Min HR Long V-Run	/	Min HR Long SV-Run	/		
Max HR Long V-Run	/	Max HR Long SV-Run	/		
VE's per 1000	1	SVE's per 1000	0		
VE's per Hour	6	SVE's per Hour	0		

Figure 127: Summary information for the report.

General information

The general information section contains information on:

- Analyzed beats – number of all R waves in the period;
- Total recording duration – the time difference before the first and last recording of the reporting period;
- Normal Sinus Rhythm Duration – the duration of the normal sinus rhythm in the recorded period.
- ECG monitoring period start – the start of the reporting period; and
- The ECG monitoring period ends at the end of the report period.

The heart rate section contains information on the following:

- Min HR-4 Intervals – the minimum average BPM value of all consecutive 4 minutes;
- Max HR-4 Intervals - the maximum average BPM value of all consecutive 4 minutes;
- Average HR-24 Hours – the average BPM value for the whole report period;
- Min HR-Hourly - the minimum average BPM value of all successive hours; and
- Max HR-Hourly – the maximum average BPM value of all consecutive hours.

The pauses and aberrant beats sections contain information on:

- SA Total – Total number of Sinus Arrest (>3sec) occurrences;

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- Maximum SA – maximum Sinus Arrest duration in sec;
- Micro SA Total – Total number of Micro Sinus Arrest (>1.5sec and <3sec) occurrences; and
- Total Aberrant Beats/Runs.

Heart rate variability

The HRV-Time domain section contains information on:

- SDNN – standard deviation of all RR intervals expressed in ms;
- ASDNN - mean value of the standard deviations of all t-minute intervals in ms;
- SDANN - standard deviation of the means of the RR intervals for all 5-minute subintervals in ms;
- NN50 - the number of RR interval differences of successive RR intervals more significant than 50 ms;
- pNN50 - NN50 as a percentage of all allowed RR intervals and
- rMSSD - root mean square of successive RR differences in ms.

The HRV-Frequency domain section contains information on:

- ULF – Energy at the ultra-low frequency band;
- VLF – Energy at the very low-frequency band;
- LF – Energy at the low-frequency band;
- HF – Energy at the high frequency band; and
- HF/LF – Ration between the energies of high and low-frequency domains.

The HRV-Time domain section contains information on:

- Poincaré SD1;
- Poincaré SD2;
- Poincaré SD1/SD2;
- DFA α_1 ; and
- DFA α_2 .

Ventricular and supraventricular sections

The ventricular ectopy section contains information on the following:

- VE Total – the total number of ventricular ectopy;
- VE-Pair Total – the total number of couplets of ventricular ectopy;
- Short V-Runs ($3 \leq n < 6$) – Number of short runs of Ventricular beats
- Long V-Run Total ($n \geq 6$) – Number of long runs of Ventricular beats
- Longest V-Run – the most extended number of successive ventricular ectopy beats exceeding 5;
- Min HR V-Run - the minimum BPM value of all ventricular ectopy runs exceeding five successive beats;
- Max HR V-Run – the maximum BPM value of all ventricular ectopy runs exceeding five successive beats;
- VE's per 1000 – the average number of ventricular ectopy per 1000 beats; and
- VE's per Hour – the average number of ventricular ectopy per hour.

The supraventricular ectopy section contains information on:

- SVE Total – the total number of supraventricular ectopy;
- SVE-Pair Total – the total number of couplets of supraventricular ectopy;

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- Short SV-Runs ($3 \leq n < 6$) – Number of short runs of SupraVentricular beats
- Long SV-Run Total ($n \geq 6$) – Number of long runs of SupraVentricular beats
- Longest SV-Run – the most extended number of successive supraventricular ectopy beats exceeding 5;
- Min HR SV-Run - the minimum BPM value of all supraventricular ectopy runs exceeding five successive beats;
- MaxHR SV-Run – the maximum BPM value of all supraventricular ectopy runs exceeding 5 successive beats;
- SVE's per 1000 – average number of supraventricular ectopy per 1000 beats; and
- SVE's per Hour – average number of supraventricular ectopy per hour.

In addition to the mandatory sections, the summary information section also has a dynamic number of subsections, one for each type of detected episode for the current measurement period. Each episode section holds information on:

- Number of episodes – number of instances of the episode;
- Total duration – the sum of individual durations of the episode of the type;
- Longest Duration – the episode with the most extended duration of the type;
- Min HR - the episode with the minimum heart rate of the type and
- Max HR - the episode with the maximum heart rate of the type.

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6.3. HRV Plot Charts

HRV Plot Charts subsection shows four square charts:

- The first chart is a bar chart with the title RR Distribution and displays the RR in seconds versus the number of beats;
- The second chart has a title: NN Spectrum and displays the Frequency versus the PSD;
- The third chart is with the title Poincaré Plot and displays the RR_n value on the x-axis in respect to the RR_{n+1} value on the y-axis and
- The fourth chart is a scatter plot titled RR Detrended Fluctuations and displays the $\log_{10}n(\text{beats})$ on the x-axis and the $\log_{10}F(n)$ on the y-axis.

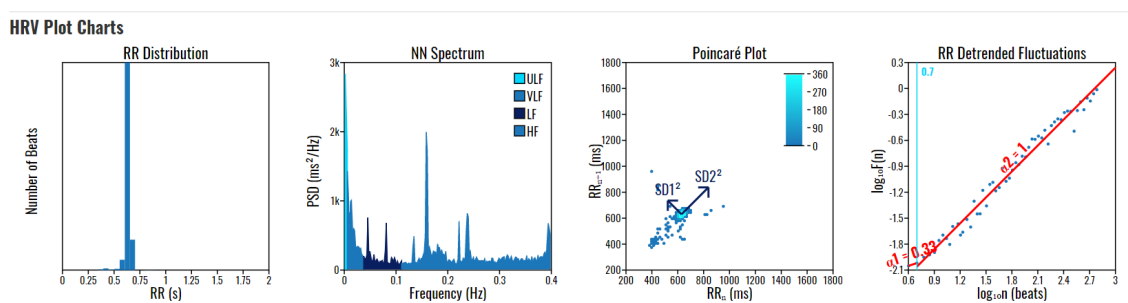


Figure 128: HRV Plot Charts

6.4. Statistics on Detected Beats and Rhythm Episodes

Detected Beats and their Annotations

The system automatically detects several beats, including premature atrial contractions (PAC), premature ventricular contractions (PVC), and fusion beats. These are presented in the dashboard (Figure 129).

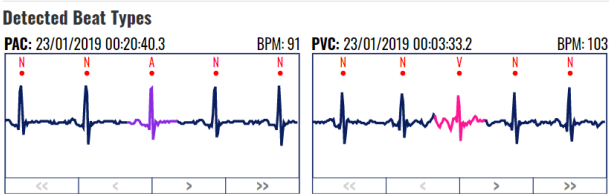


Figure 129: Detected beats and their annotations.

This section provides an information box for each annotation detected in the report period. The annotation box contains the annotation's abbreviated name, an ECG strip of the annotation, and navigation buttons below the ECG strip (first annotation in the current period, previous annotation, next annotation, and last annotation in the current period).

The annotation abbreviation and the annotation ECG strip have tooltip information on mouse over with the full name of the annotation. A navigation button can be inactive if such annotation does not exist. Suppose the content section width is insufficient to fit all annotation information boxes. In that case, the content section is extended in height, meaning a new line of annotation information boxes will be listed. By clicking the annotation strip, an ECG strip with the same type of annotation will be shown in the annotation box if the following annotation exists. The current annotation will be displayed when the report is printed, or the report is saved and reopened.

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Detected Rhythm Episodes

The system automatically detects several types of rhythm episodes (Figure 130), including Atrial fibrillation (AFIB), ventricular tachycardia (VT), supraventricular tachycardia (SVTA), Bigeminy (B), and Trigeminy (T).

This section provides an information box for each episode detected in the report period. The episode box contains the episode's abbreviated name, an ECG strip of the episode, and navigation buttons below the ECG strip (first episode in the current period, previous episode, next episode, and last episode in the current period).



Figure 130: Detected rhythm episodes.

The episode abbreviation and the episode ECG strip have tooltip information on mouse over with the full name of the episode. A navigation button can be inactive in case such an episode does not exist. Suppose the content section width is insufficient to fit all episode information boxes. In that case, the content section is extended in height, meaning a new line of episode information boxes will be listed.

By clicking the episode strip, an ECG strip with the next episode of the same type will be shown in the box if the next such episode exists. The current episode will be shown when the report is printed or the report is saved and reopened.

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6.5. Histograms and Selected ECG Strips

Significant Histograms

The report contains a section with significant histograms displayed (Figure 131).

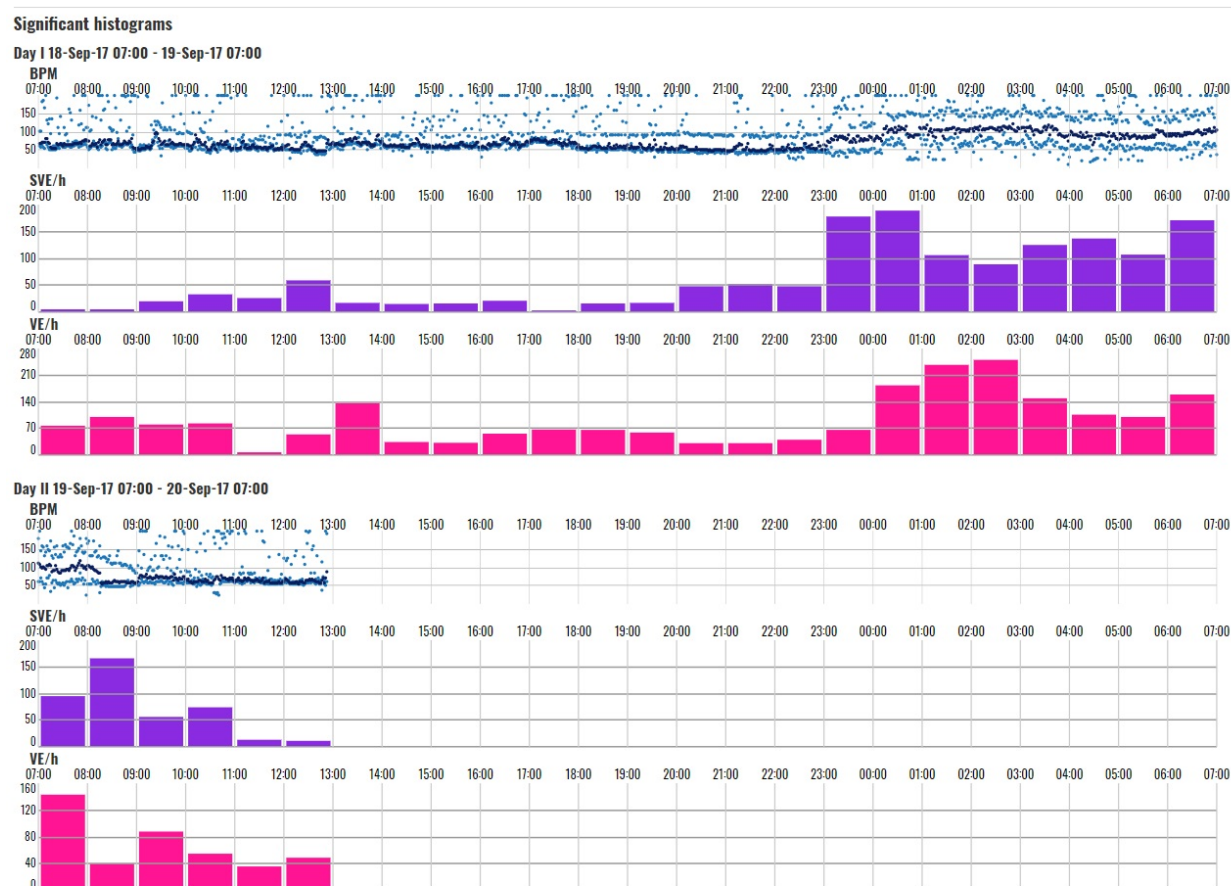


Figure 131: Significant histograms presented in the report.

For each day from the chosen period, a group of histogram charts are rendered:

- BPM chart – a daily BPM chart is drawn; the visualization resembles the hour selector section from the monitoring section;
- SVE/h - the supraventricular ectopy annotations are grouped and an hourly column histogram is drawn;
- VE/h - the ventricular ectopy annotations are grouped and an hourly column histogram is drawn;
- SA/h - hourly column histogram for the sinoatrial arrests; and
- MSA/h - hourly column histogram for the micro sinoatrial arrests.

If all the values in the column histogram are zero, the column histogram is omitted. On mouse over events on the column histogram columns, there is tooltip information on the number of annotation occurrences. The beginning of the time series does not begin at 00:00:00, but it is relative to the start of the first recording period within the day and lasts 24 hours.

Events

Significant events can be shown in the report (Figure 132). The header contains the event's date, start time, place, activity, feeling and the sensor position. Below are the ECG strips forming the event. The doctor can add a note to the event or delete it with a click to the appropriate button.

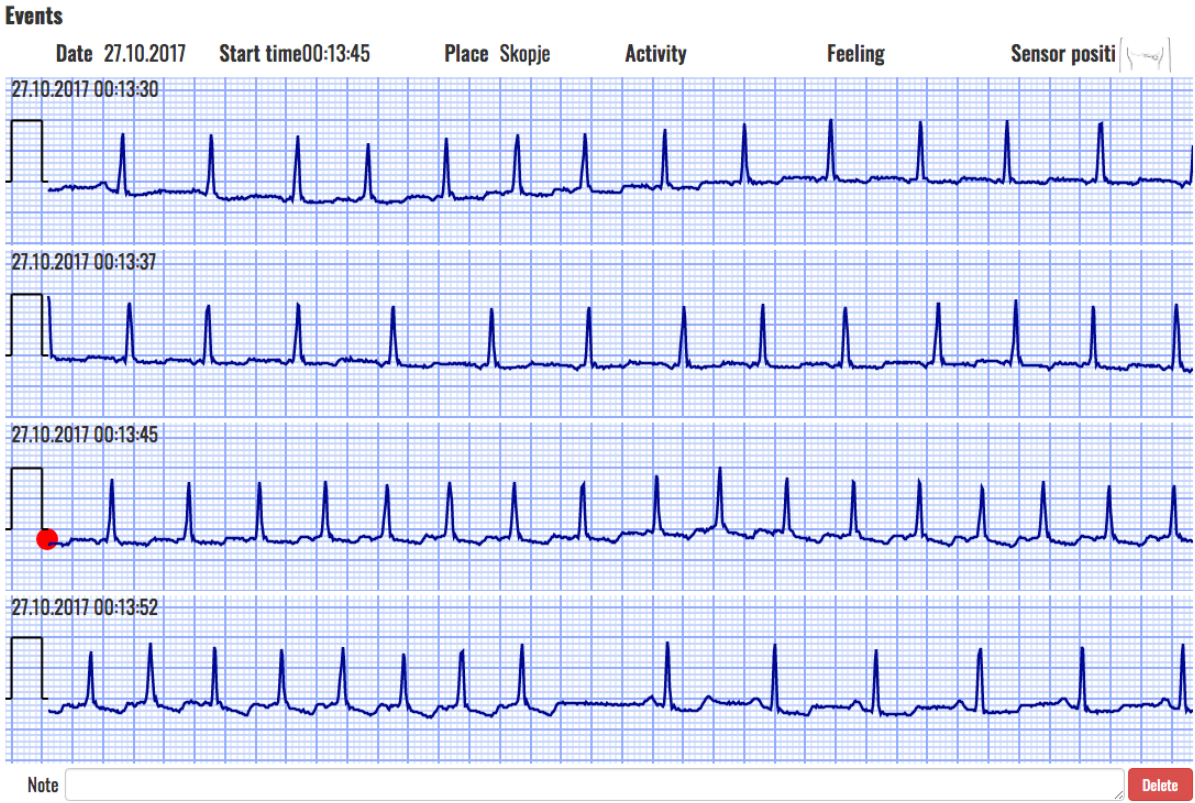


Figure 132: Significant events presented in the report.

Selected Segments

This section provides the list of selected ECG strip segments by the doctor using the monitoring page. The ECG strips are 7.5, 15, or 30 seconds long. Each row is 7.5 seconds long, so a strip can span multiple rows. Each ECG strip is drawn with the standardized ECG grid and begins with the standard tick symbol.

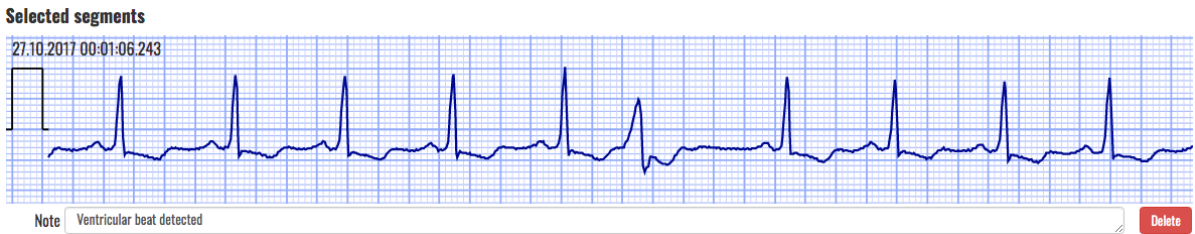


Figure 133: Selected segments presented in the report.

The doctor can add a comment for each ECG strip. The strip can also be removed from the report by clicking the accompanying delete button.

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6.6. Report Edit

A doctor's report can be accessed to edit certain specifications (Figure 134). Hovering over the desired section of the report, the edit button will appear. Clicking the edit button will allow editing parts of the report. Values of the report that can be edited will be shown in a blue rectangle. Simple select and edit actions will modify the selected value.

Summary Information		Summary Information	
GENERAL INFORMATION		GENERAL INFORMATION	
Analyzed Beats	52512	Analyzed Beats	52512
Total Recording Duration	14:34:39	Total Recording Duration	14:34:39
Normal Sinus Rhythm Duration	(77.62%) 11:18:54	Normal Sinus Rhythm Duration	(77.62%) 11:18:54
ECG Monitoring Start	20.11.2016 17:27:00	ECG Monitoring Start	20.11.2016 17:27:00
ECG Monitoring End	21.11.2016 08:02:30	ECG Monitoring End	21.11.2016 08:02:30

Figure 134: Edit button.

General Information

The General Information section in the report has the option for editing the following values:

- Normal Sinus Rhythm Duration.

The heart rate section in the report has the option for editing the following values:

- Min HR-4 Intervals;
- Max HR-4 Intervals;
- Average HR-24 Hours;
- Min HR-Hourly; and
- Max HR-Hourly.

The pauses and aberrant beats sections in the report have the option for editing the following values:

- SA Total;
- Maximum SA;
- Micro SA Total; and
- Total Aberrant Beats/Runs.

Heart Rate Variability

The HRV-Time domain section in the report has the option for editing the following values:

- SDNN;
- ASDNN;
- SDANN;
- NN50; and
- rMSSD.

Ventricular and Supraventricular Sections

The ventricular ectopy section in the report has the option for editing the following values:

- VE Total;
- VE-Pair Total;
- Short V-Runs ($3 \leq n < 6$);
- Long V-Run Total ($n \geq 6$);
- Longest V-;
- Min HR V-Run;

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- Max HR V-Run;
- VE's per 1000; and
- VE's per Hour.

The supraventricular ectopy section in the report has the option for editing the following values:

- SVE Total;
- SVE-Pair Total;
- Short SV-Runs ($3 \leq n < 6$);
- Long SV-Run Total ($n \geq 6$);
- Longest SV-Run;
- Min HR SV-Run;
- MaxHR SV-Run;
- SVE's per 1000; and
- SVEs per Hour.

The summary information section in the report has the option for editing the following values:

- Number of episodes;
- Total duration;
- Longest Duration;
- Min HR; and
- Max HR.

The summary information section in the report also has the option for deleting all information and the entire section (Figure 135). A confirmation for deletion is required (Figure 136)



Figure 135: Delete button.

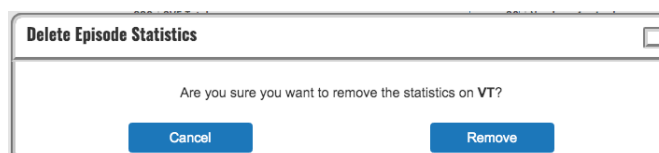


Figure 136: Confirmation for deletion of episode statistics.

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6.7. Writing Opinion and File Management

Opinion

The report opinion has a default preset template in the following format (Figure 137):

“The total recording time is <recording time>. The basic rhythm is <most common rhythm episode>.

Heart rate ranged from <min bpm> bpm at <min bpm time stamp>, to <max bom> bpm at <max bpm timestamp>, while the mean value is <average bpm> bpm.

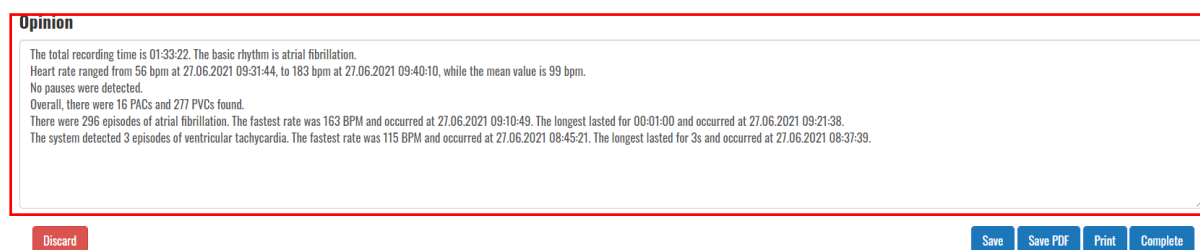
<Number of pauses> pauses were detected.

Overall, <PAC number> PACs and <PVC number> PVCs were found.

<FOR EACH EPISODE TYPE BEGIN>

There were <number of the episode type> episodes of <episode type name>. The fastest rate was <episode type max bpm> and occurred at <episode type max bpm time stamp>. The longest lasted for <episode type longest duration> and occurred at <episode type longest duration time stamp>.

<FOR EACH EPISODE TYPE END>”



Opinion

The total recording time is 01:33:22. The basic rhythm is atrial fibrillation.
Heart rate ranged from 56 bpm at 27.06.2021 09:31:44, to 183 bpm at 27.06.2021 09:40:10, while the mean value is 99 bpm.
No pauses were detected.
Overall, there were 16 PACs and 277 PVCs found.
There were 296 episodes of atrial fibrillation. The fastest rate was 163 BPM and occurred at 27.06.2021 09:10:49. The longest lasted for 00:01:00 and occurred at 27.06.2021 09:21:38.
The system detected 3 episodes of ventricular tachycardia. The fastest rate was 115 BPM and occurred at 27.06.2021 08:45:21. The longest lasted for 3s and occurred at 27.06.2021 08:37:39.

Discard Save Save PDF Print Complete

Figure 137: Form to write an opinion in the report.

The doctor enters their opinion for the report in the input text field at the bottom of the review page.

Action Buttons

File management functions for the report are available via action buttons at the bottom of the report page (Figure 138).



Opinion

The total recording time is 01:33:22. The basic rhythm is atrial fibrillation.
Heart rate ranged from 56 bpm at 27.06.2021 09:31:44, to 183 bpm at 27.06.2021 09:40:10, while the mean value is 99 bpm.
No pauses were detected.
Overall, there were 16 PACs and 277 PVCs found.
There were 296 episodes of atrial fibrillation. The fastest rate was 163 BPM and occurred at 27.06.2021 09:10:49. The longest lasted for 00:01:00 and occurred at 27.06.2021 09:21:38.
The system detected 3 episodes of ventricular tachycardia. The fastest rate was 115 BPM and occurred at 27.06.2021 08:45:21. The longest lasted for 3s and occurred at 27.06.2021 08:37:39.

Discard Save Save PDF Print Complete

Figure 138: Action buttons for file management.

The bottom left corner of the page has an action button that deletes the report. In the bottom right corner, there is an action button that saves the report, one that completes it, and one that allows printing of the report.

Report Printing

The user enters the printing dialogue form by clicking the “Print” button (Figure 139).

Opinion

The total recording time is 01:33:22. The basic rhythm is atrial fibrillation.
Heart rate ranged from 56 bpm at 27.06.2021 09:31:44, to 183 bpm at 27.06.2021 09:40:10, while the mean value is 99 bpm.
No pauses were detected.
Overall, there were 16 PACs and 277 PVCs found.
There were 296 episodes of atrial fibrillation. The fastest rate was 163 BPM and occurred at 27.06.2021 09:10:49. The longest lasted for 00:01:00 and occurred at 27.06.2021 09:21:38.
The system detected 3 episodes of ventricular tachycardia. The fastest rate was 115 BPM and occurred at 27.06.2021 08:45:21. The longest lasted for 3s and occurred at 27.06.2021 08:37:39.

Discard

Save

Save PDF

Print

Complete

Figure 139: Print button to activate the printing dialogue.

The report dialogue form (Figure 140) is immediately opened after activating the print functionality. The user can choose to print the report to a printer device, save it as a PDF (browser-dependent), or export it in another manner (browser- and extension-dependent).

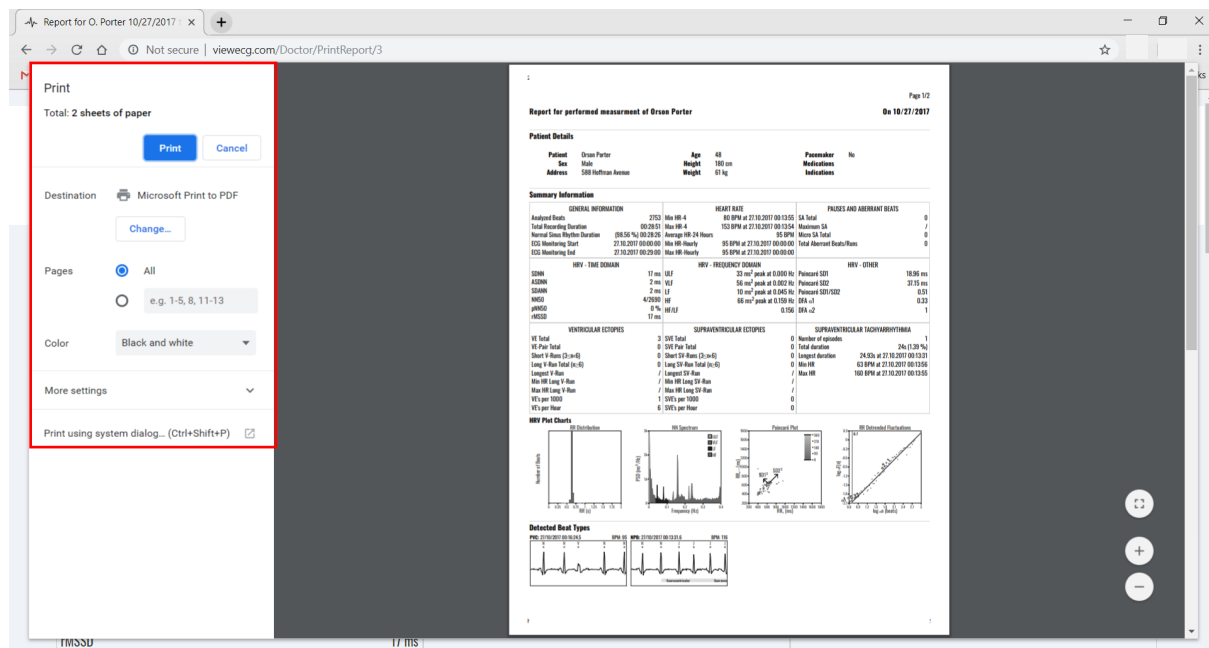


Figure 140: Print dialogue form.

The print report page resembles the report generation page with a few differences:

- The report generation page header is removed and replaced by a report print page header,
- The measurement period section is gone,
- The list of identified annotations and episodes does not have navigation buttons,
- The opinion content is not editable,
- The doctor's name and the timestamp of the report creation date can be found below the doctor's opinion section, and
- The colors have been reduced to grayscale, with an emphasis on higher contrast, so that the report can be printed optimally on grayscale printers.

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 VIEWECG - THE PHYSICIAN MUST REVIEW THE REPORT DATA

Report Date: 19/10/2020 Page 1/2

Automated Report for A. Spasovska

On 27/06/2021

Patient Details

Patient	Ana Spasovska	Age	30	Pacemaker	No
Sex	Female	Height	170 cm	Medications	
Address	588 Hoffman Avenue	Weight	55 kg	Indications	

Figure 141: Printed report sample header.

The report print header is placed on top of every page, and it contains the following information:

- Logo;
- Page number indicator;
- Patient's full name and
- Measurement period.

Opinion

The total recording time is 01:33:22. The basic rhythm is atrial fibrillation.

Heart rate ranged from 56 bpm at 27.06.2021 09:31:44, to 183 bpm at 27.06.2021 09:40:10, while the mean value is 99 bpm.

No pauses were detected.

Overall, there were 16 PACs and 277 PVCs found.

There were 296 episodes of atrial fibrillation. The fastest rate was 163 BPM and occurred at 27.06.2021 09:10:49. The longest lasted for 00:01:00 and occurred at 27.06.2021 09:21:38.

The system detected 3 episodes of ventricular tachycardia. The fastest rate was 115 BPM and occurred at 27.06.2021 08:45:21. The longest lasted for 3s and occurred at 27.06.2021 08:37:39.

19/10/2020 13:44:59



ViewECG Medical Device CE Mark 1304, no. MDD-167, Med Directive 93/42, Valid Until 2024-06-30

Figure 142: Printed report sample footer.

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7. Data Formatting

The Physionet specification for annotations has been supplemented with additional information, such as beat and episode types and color, to meet the necessary application requirements for data presentation.

7.1. Beat Annotations

Each ECG beat annotation type has the following properties:

- Name – The full name of the ECG beat type;
- Abbreviation – An abbreviation of the full name of the ECG beat type, often used in the dashboard sections for practical purposes;
- Sign – The sign used to represent the type of ECG beat, usually used in ECG signal charts;
- Wave – Indicates to which physiological ECG wave type the ECG beat belongs to out of the following: P, Q, R, S, T, O (other);
- Color – The color indicator for the ECG beat. The color representation helps the interpreter intuitively read the ECG beat type without paying attention to the sign. The color representation of the beats helps most while examining the list of ECG strips on the monitoring page. Not all ECG beat annotations are associated with color, i.e. some of the beat annotations will have the default signal color.
- InBPM – Indicates whether the ECG beat is included in the calculation of BPM;
- InDashboard – Indicates whether statistical information of the wave type will be included in a dashboard section;
- InReport – Indicates whether statistical information of the wave type will be included in a report form;
- InVEGroup – Indicates whether the ECG beat is part of the Ventricular Ectopy (VE) group of beats and
- InSVEGroup – Indicates whether the ECG beat is part of the Supraventricular Ectopy (SVE) group of beats;

Name	Abbreviation	Sign	Wave	Color	InBPM	InDashboard	InReport	InVEGroup	InSVEGroup
Normal	Normal	N	R		TRUE	FALSE	FALSE	FALSE	FALSE
Premature atrial contraction	PAC	A	R		TRUE	TRUE	TRUE	FALSE	TRUE
Premature ventricular contraction	PVC	V	R		TRUE	TRUE	TRUE	TRUE	FALSE
Left bundle branch block beat	LBBB	L	R		TRUE	TRUE	FALSE	FALSE	FALSE
Right bundle branch block beat	RBBB	R	R		TRUE	TRUE	FALSE	FALSE	FALSE
Bundle branch block beat (unspecified)	BBB	B	R		TRUE	TRUE	FALSE	FALSE	FALSE
Aberrated atrial premature beat	AAPB	a	R		TRUE	TRUE	FALSE	FALSE	TRUE
Nodal (junctional) premature beat	NPB	J	R		TRUE	TRUE	FALSE	FALSE	FALSE
Supraventricular premature or ectopic beat (atrial or nodal)	SPEB	S	R		TRUE	TRUE	FALSE	FALSE	TRUE
R-on-T premature ventricular contraction	RTPVC	r	R		TRUE	TRUE	FALSE	FALSE	FALSE

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Name	Abbreviation	Sign	Wave	Color	InBPM	InDashboard	InReport	InVEGroup	InSVEGroup
Fusion of ventricular and normal beat	FVNB	F	R		TRUE	TRUE	FALSE	TRUE	FALSE
Atrial escape beat	AEB	e	R		TRUE	TRUE	FALSE	FALSE	TRUE
Nodal (junctional) escape beat	NEB	j	R		TRUE	TRUE	FALSE	FALSE	FALSE
Supraventricular escape beat (atrial or nodal)	SEB	n	R		TRUE	TRUE	FALSE	FALSE	TRUE
Ventricular escape beat	VEB	E	R		TRUE	TRUE	FALSE	TRUE	FALSE
Paced beat	PB	/	R		TRUE	TRUE	FALSE	FALSE	FALSE
Fusion of paced and normal beat	FPNB	f	R		TRUE	TRUE	FALSE	FALSE	FALSE
Unclassifiable beat	UB	Q	R		TRUE	TRUE	FALSE	FALSE	FALSE
Beat not classified during learning	BNCDL	?	R	/	TRUE	FALSE	FALSE	FALSE	FALSE
Sinus Arrest (Pause)	SA Pause	P	R		TRUE	FALSE	FALSE	FALSE	FALSE
Start of ventricular flutter/fibrillation	VFIB Start	[O	/	FALSE	FALSE	FALSE	FALSE	FALSE
End of ventricular flutter/fibrillation	VFIB End]	O	/	FALSE	FALSE	FALSE	FALSE	FALSE
Ventricular flutter wave	VF Wave	!	R	/	TRUE	TRUE	FALSE	FALSE	FALSE
Peak of T-wave	T Wave	t	T	/	FALSE	FALSE	FALSE	FALSE	FALSE
Peak of P-wave	P Wave	p	P	/	FALSE	FALSE	FALSE	FALSE	FALSE
Isolated QRS-like artifact	QRS Artifact	l	R	/	FALSE	TRUE	FALSE	FALSE	FALSE
Change in signal quality	Quality Change	C	O	/	FALSE	FALSE	FALSE	FALSE	FALSE
Rhythm change	Rhythm Change	+	O	/	FALSE	FALSE	FALSE	FALSE	FALSE
Comment annotation	Comment	Z	O	/	FALSE	FALSE	FALSE	FALSE	FALSE
Peak of Q-wave	Q Wave	q	Q	/	FALSE	FALSE	FALSE	FALSE	FALSE
Peak of S-wave	S Wave	s	S	/	FALSE	FALSE	FALSE	FALSE	FALSE
ST change	ST Change	o	S	/	FALSE	FALSE	FALSE	FALSE	FALSE
T-wave change	T Change	x	T	/	FALSE	FALSE	FALSE	FALSE	FALSE
Systole	Systole	z	O	/	FALSE	FALSE	FALSE	FALSE	FALSE
Diastole	Diastole	d	O	/	FALSE	FALSE	FALSE	FALSE	FALSE
Measurement annotation	Measurement Ann	O	O	/	FALSE	FALSE	FALSE	FALSE	FALSE
Non-conducted pacer spike	Non-conducted PB	h	R	/	FALSE	TRUE	FALSE	FALSE	FALSE
U-wave peak	U Wave	u	U	/	FALSE	FALSE	FALSE	FALSE	FALSE
Learning	Learning	l	O	/	FALSE	FALSE	FALSE	FALSE	FALSE
Non-conducted P-wave (blocked APB)	Blocked APB	y	P	/	FALSE	FALSE	FALSE	FALSE	FALSE
Waveform onset	WF Onset	W	O	/	FALSE	FALSE	FALSE	FALSE	FALSE
Waveform end	WF End	w	O	/	FALSE	FALSE	FALSE	FALSE	FALSE
Micro sinus arrest (pause)	Micro SA Pause	M	R	/	TRUE	FALSE	FALSE	FALSE	FALSE
Micro sinus arrest (pause)	Micro SA Pause	b	R	/	TRUE	FALSE	FALSE	FALSE	FALSE
Unidentified	Unidentified	U	R		FALSE	TRUE	FALSE	FALSE	FALSE

7.2. Detected Rhythm Episodes

Each ECG episode annotation type has the following properties:

- **Name** – The full name of the ECG episode;
- **Abbreviation** – An abbreviation of the full name of the ECG episode; often used in the dashboard sections due to practical purposes (sometimes this abbreviation is presented with preceding “(“in the ECG charts);
- **Color** – The color indicator for the ECG episode. The color representation helps the interpreter intuitively read the ECG episode type without paying attention to the sign. The color representation of the episodes helps most while examining the list of ECG strips on the monitoring page. Not all ECG episode annotations have a color;
- **InDashboard** – Indicates whether statistical information of the episode type will be included in a dashboard section; and
- **InReport** – Indicates whether statistical details of the episode type will be included in a report form.

Name	Abbreviation	Color	InDashboard	InReport
Normal	N	/	FALSE	FALSE
Atrial bigeminy	AB		TRUE	TRUE
Atrial fibrillation	AFIB		TRUE	TRUE
Atrial flutter	AFL		TRUE	TRUE
Ventricular bigeminy	B		TRUE	TRUE
2° heart block	BII		TRUE	TRUE
Idioventricular rhythm	IVR	/	TRUE	TRUE
Nodal (A-V junctional) rhythm	NOD		TRUE	TRUE
Paced rhythm	P		TRUE	TRUE
Pre-excitation (WPW)	PREX	/	TRUE	TRUE
Sinus bradycardia	SBR		TRUE	TRUE
Supraventricular tachyarrhythmia	SVTA		TRUE	TRUE
Ventricular trigeminy	T		TRUE	TRUE
Ventricular flutter	VFL		TRUE	TRUE
Ventricular tachycardia	VT		TRUE	TRUE
Noise	NOISE		FALSE	FALSE
No signal	NOSIGNAL		FALSE	FALSE

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8. How to Use the Monitoring Center Functions?


Given that a doctor or an expert in the medical monitoring center is a registered user, the standard login functions explained earlier are used to log in to the web application.

Menu options are:

- Dashboard,
- Patients,
- Alerts.

System Health-related Events

After initial login, the doctor in the monitoring center should view a list of all current and unresolved health-related events, which should be clickable (Figure 143).



High risk (1)			
A223 568 d 19 : 19 : 11	VT		
Medium risk (4)			
A221 569 d 09:30	AFIB	A210 569 d 09:30	AFIB
		A205 569 d 09:25	VT
		A219 569 d 09:24	AFIB
Low risk (3)			
A207 569 d 09:30	B	A200 569 d 09:21	B
		A208 569 d 09:13	T
Online (0)			
Offline (73)			

Figure 143: All system health-related events

All resolved events should be stored in an archive. When activated, this option lists all events and their status if the doctor has set a corresponding diagnosis or recommendation.

Monitor and Resolve a Health-related Event

When an event is clicked, the doctor in the monitoring center should see the patient, his location, and his latest ECG scan.

The How to use the monitoring tools section presents the corresponding monitoring tools details.

Upon each event, the doctor can resolve it by clicking the urgency degree to be immediate (call an ambulance), medium (visit a doctor in 24h), low (visit a doctor in three days), and irrelevant (false alarm).

In this case, the health-related event is resolvable and removed from the list of events.

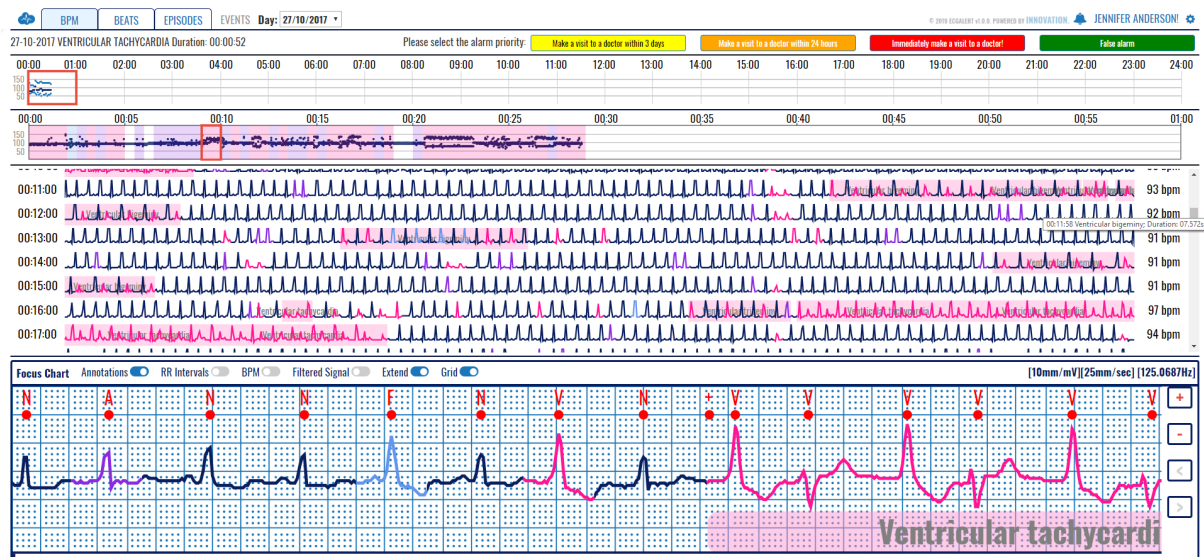


Figure 144: Health-related event monitoring