

ViewECG

Medical device system

Doctor's User Manual



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This user manual refers to the ViewECG software version 1.1.5 from 02.12.2021

Revision 9 | 04 April 2023



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READ THIS FIRST

First read the safety measures from the Patient's [User Manual](#).



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1. Product Description

ViewECG is a medical device for real-time long-term ECG monitoring. The medical device is distributed as a Software-as-a-Service platform for online ECG monitoring. Users are able to measure their ECG with the use of a light wearable sensor and their smartphone, and get reviewed by their doctor in real-time. Any abnormal function is automatically annotated by the software and confirmed with the help of a medical expert.

The ViewECG medical device software contains five software chapters (applications):

- **ViewECG-M is an iOS mobile application**, which is a heart monitoring application that connects to Savvy sensor, receives ECG data, visualize recorded data and sends files to the cloud system for further processing, defined as defined as **accessory** according to MDD 93/42/EEC Article 1 paragraph 2(b), i.e., according to Article 2, paragraph 2 from MDR 2017/745.).
- **ViewECG-C is a cloud monitoring application**, that collects ECG signals, and enables a tool for doctors and patients to monitor ECGs in real time with warning functions and also postponed reporting, defined as **medical device** according to MDD 93/42/EEC Article 1 paragraph 2(a), i.e., according to Article 2, paragraph 2 from MDR 2017/745.).
- **ViewECG-D is an ECG diagnostic software**, that accepts ECG signals, process them by DSP filtering, QRS heartbeat detection, beat classification and episode determination, defined as **accessory** according to MDD 93/42/EEC Article 1 paragraph 2(b), i.e., according to Article 2, paragraph 2 from MDR 2017/745.).
- **ViewECG-H is an ECG monitoring (Holter) software**, that presents a dashboard, histograms, ECG signals in a continuous way to enable a platform for the doctor to produce a clinical review, defined as **accessory** according to MDD 93/42/EEC Article 1 paragraph 2(b), i.e., according to Article 2, paragraph 2 from MDR 2017/745.).
- **ViewECG-V is an ECG visualization software** that contains a set of scripts with SVG vector graphics to display the ECG, defined as **accessory** according to MDD 93/42/EEC Article 1 paragraph 2(b), i.e., according to Article 2, paragraph 2 from MDR 2017/745.).

ViewECG medical device system is categorized by the **UMDNS code number 13988 – ECG Monitoring, Telemetric.**

ViewECG is categorized as safety class **Class A: No injury or damage to health is possible** according to the harmonized standard and technical specification **EN ISO 62304:2006/A1:2015** with the intended use of:

- real-time long-term ECG monitoring, and
- providing information of possible arrhythmia upon which a registered medical expert will interpret the recorded ECG, create a relevant report and conduct other specific medical procedures to make a proper diagnosis of an onset of the indicated arrhythmia.

2. General

The purpose of this user manual is to provide the user that has been provided the doctor's role, insight on the web application functionalities by explaining the interfaces and different use-case scenarios, as well as information on the format and constitution of the ECG feature findings.

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The doctor can access information only for patients assigned during the patient's registration. In addition, the doctor can create new patients and upload their recorded ECG file.

The monitoring and report presentation tools are described in detail with emphasis on instructions on how to navigate and access relevant parts for effortless interpretation.

A section is dedicated to report creation with directions on how to generate a report, alter any inconsistent or incorrect findings and make general assessment of medical data for a given extend of recorded ECG.

2.1. Prescribed Use

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

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

2.2. Intended users

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

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

Table 1: Users and roles

2.3. Indications

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

2.4. Contraindications

ViewECG is not intended for use by individuals who require hospital monitoring of a life-threatening arrhythmia. It is intended for personal use to measure and monitor ECG. The associated ECG sensor has contact with the human skin through the adhesive electrodes, so users should apply the instruction of use for that device and read carefully the corresponding contraindications. For example, individuals that do not know how to use a smartphone need supervised use of the medical device by a caregiver.

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2.5. Clinical Benefits

Long-term ECG monitoring has become an indispensable technology for prevention, management and treatment of many cardiac disorders¹. The diagnoses of syncope or non-sustained rhythm disturbances remain a difficult task in clinical cardiology, leading to multiple out-patient visits, multiple examinations, diagnostic tests and unnecessary hospitalizations². In light of this, all recent Guidelines for the management of: Syncope, Atrial fibrillation, Ventricular arrhythmia and prevention of Sudden Cardiac Death³ recommended prolonged ECG monitoring - for detection of asymptomatic rhythm disturbances or to correlate symptoms to ECG finding.

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

The most important clinical benefit of ViewECG is the large diagnostic yield. Namely, the diagnostic yield of external monitoring systems goes up to 50% in cases where the duration of monitoring is 1 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.

2.6. Labelling

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

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

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

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

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

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

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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 1.1.5

Published on 02.12.2021

Device labelling

CE 1304

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



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Figure 1: ViewECG marking for CE number.

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

3. User requirements

3.1. Interpretational skills for doctors

The user is required to have advanced expertise in non-invasive cardiology for interpretation of the ECG findings. Experience with ECG monitoring software would provide a significant advantage in interpreting the findings. The web-application interfaces follow the classic design principles; hence, the user needs to be averagely acquainted with such applications in order to intuitively manage the monitoring functionalities of the web application. A thorough read of the manual is recommended to make the most of the supported functionalities. The ECG findings are in accordance with the Physionet standard⁶ for annotations and episodes.

3.2. Digital device

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

ViewECG is compatible with the following smartphones and tablets:

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

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

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

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

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

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

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ViewECG.

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

3.3. User requirements for the Web Application

Web browser-enabled computing device

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

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

The hardware requirements of the computing device are:

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

The requirements for the printing unit are:

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

The constraints for relatively good graphics performance include:

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

The requirements for the operating system and web browser include:

- Any modern operating system can support sufficient performance, including Mac OS, Microsoft Windows, Linux, IOS, Android or similar;
- Web browser that supports Scalar Vector Graphics (SVG) satisfy the minimum requirements for web browsing. Tested web browsers are Safari 13.1.2 (13609.3.5.1.5) and higher versions. 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.

3.4. Register and login

The doctor needs to be registered by the service provider in order to gain access to the [web application](#). A standard login procedure with username and password is applied to enter the home page.

3.5. Maintenance, compliance, troubleshooting and cautions

These headings are explained further in the patient's [user manual](#).

4. How to use the web application as a Doctor

The doctor logs in the web application with valid credentials and the doctor's home page is displayed.

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 displays the doctor's list of patients (Figure 1).

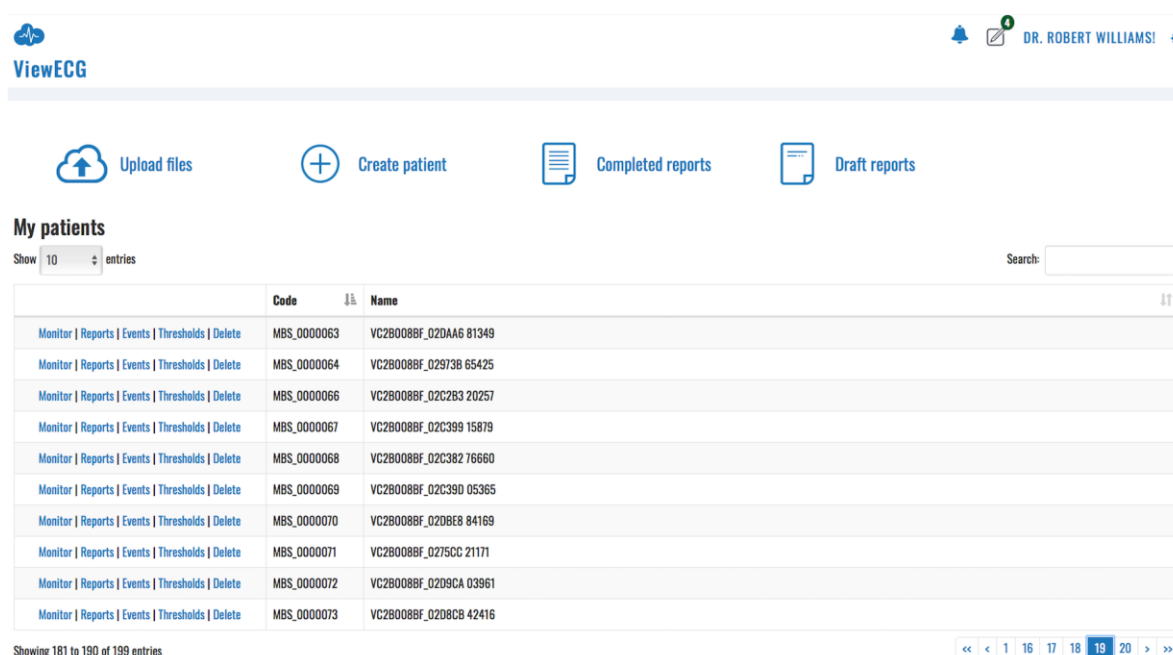


Figure 1: Doctor's home page is by default a list of patients.

My patients' page header

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

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

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

A link to "Draft reports" will appear next to the "Alarm icon" if there are any started reports that have not been completed. 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 link to the account details page.

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

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List of patients

My patients' list (Figure 1) presents only 10 last patients as a default option.

The user can adjust the preferred number of patients that will be displayed in the list by clicking on the drop-down menu next to the "Show entries" message (Figure 2) below the heading "My patients".

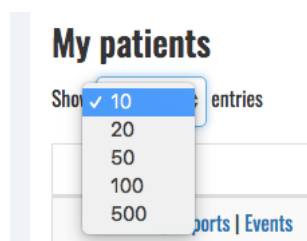


Figure 2: Selecting number of entries displayed in the list.

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 patient's code and the list will be filtered showing only those patients whose name or code contains the text entered in the search box.

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

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



Figure 3: List of navigation buttons.

The next page with selected number of patients can be displayed by clicking on the consecutive page number, or on a navigation button. The displayed navigation buttons (Figure 3) can be:

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

There is an information line at the bottom left corner that 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 4).

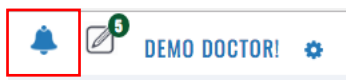


Figure 4: Alarm icon.

It is a link to the “System notifications”. In case there are pending system notifications, there is a notification number shown in the tip right corner of the icon. If there are no new system notifications, then 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 on top of the notification list and are visually distinctive.

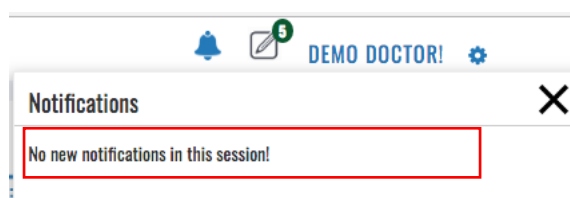


Figure 5: No new system notification.

A “System notification” may include a message that there are: “No new notifications in the session” (Figure 5), the “ECG file is successfully uploaded” and the corresponding processing has started, or “Processing finished successfully.” (Figure 6), so the user can monitor the uploaded ECG file.

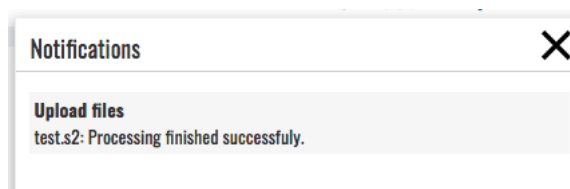


Figure 6: System notification that the processing finished and ECG is ready for monitoring.

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

Draft reports

The “Draft reports” icon is located next to the alarm icon in the header’s top right corner (Figure 7). The number in the right top corner of the draft report icon shows how many reports have not been completed, example indicates 5 draft reports. In case there are no draft reports, the “Draft reports” icon will not be displayed.

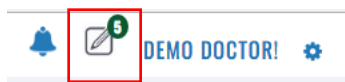


Figure 7: Draft reports' icon.

A click on the “Draft report’s icon” will display a list of draft reports (Figure 8) that have been started and are not completed. You can access and overview the list of draft reports by standard interfaces whose behavior is 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 8: List of draft reports.

Each row in the table contains a selection column, 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 9: Confirmation of draft report deleting.

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 report completion. The reporting tools are explained in the corresponding Reporting section.

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Settings

A click on “Settings icon” found at the top most right corner will activate the corresponding drop-down menu (Figure 10). The drop-down menu consists of link to the “Profile” page and “Log off” link.

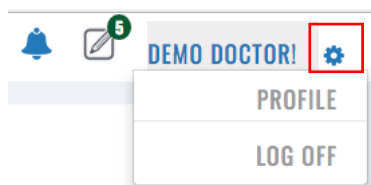


Figure 10: Settings menu options.

You can access the account details page (Figure 11) 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."/> First name <input type="text" value="Demo"/> Last name <input type="text" value="Doctor"/> Sex <input type="radio"/> Male <input checked="" type="radio"/> Female Date of birth <input type="text" value="01/01/1995"/> Address <input type="text" value="Broadway 23/25"/> City <input type="text" value="London"/> 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	User name (Email) <input type="text" value="doctor@ecgalert.com"/> Password Change your password Code <input type="text"/> Language <input type="text" value="English (United Kingdom)"/> Picture <input type="button" value="Choose file"/> No file chosen <input type="checkbox"/> Remove file <input type="button" value="Save"/>
---	--

Figure 11: Profile settings page.

The doctor can change personal data, including title, first and last name, sex, birth date, address, city, post code, country, phone number, username, password, language. In addition, the doctor can insert a photo, 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" allows 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 most used functions, including links to “Create patient”, “Upload ECG files”, list “Completed reports” and “Analysis”.



Figure 12: Most used functions

Upload files

A click on menu option “Upload files” will display the Upload files form (Figure 13). You can choose a patient on the drop-down menu or create a new patient by a click 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 13: Upload files form.

Clicking the active button “Browse” will open a file browser window (Figure 14) used for selection of one or several files to be uploaded.

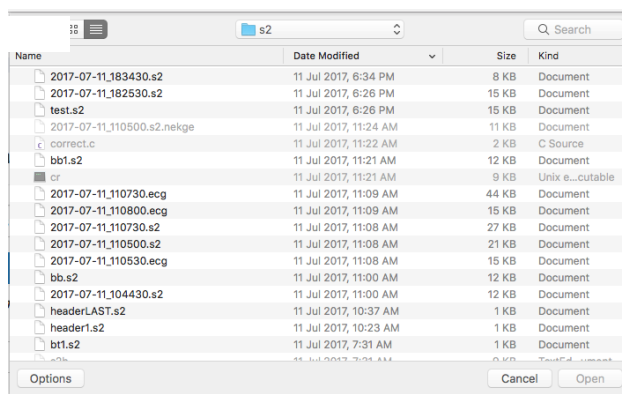


Figure 14: File browsing dialog form to select an ECG or S2 file for upload.

After selecting the files, the upload will start by clicking the action button “Start transferring”. A notification count will appear on the “Notification icon” when the upload is done. The user will get another notification as soon as the processing of the file(s) is done. The notification details can be accessed by clicking the “Notification icon”.

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Create patient

This page (Figure 15) is accessed upon click on “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, use of pacemaker, 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

First name

Last name

Date of birth

Sex ☒ Male ☐ Female

Weight

Height

Arrived on

Device

Email

Password

Confirm password

Pacemaker ☐

Indications

Medications

Company

[Back to list](#)

Figure 15: Create patient form.

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

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Completed Reports

The list of completed reports (Figure 16) is accessed by clicking on 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 16: List of completed reports.

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

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

A click on the link “Back to list” will go back 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 in 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.

Draft reports

The link leads to the Draft reports described before.

4.3. Events

List of events

The list of events page (Figure 17) is accessible either by clicking the “Events” link next to the patient’s name in the list of the 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		
20.07.2017	13:45:20		

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

[Back](#)

Figure 17: 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 sub-heading, 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 sub-heading contains also 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 on top of the list. Each line displays the date and time, and optional activity or feeling in case the user has entered them while recording the event.

You can change the number of entries to be shown by clicking on the corresponding drop-down menu next to “Show entries” label. The search field is used 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 on the appropriate date/time on the displayed list.

Overview of an event

The “Events details” page is used to overview a recorded event (Figure 18).

The overview contains a heading with 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.

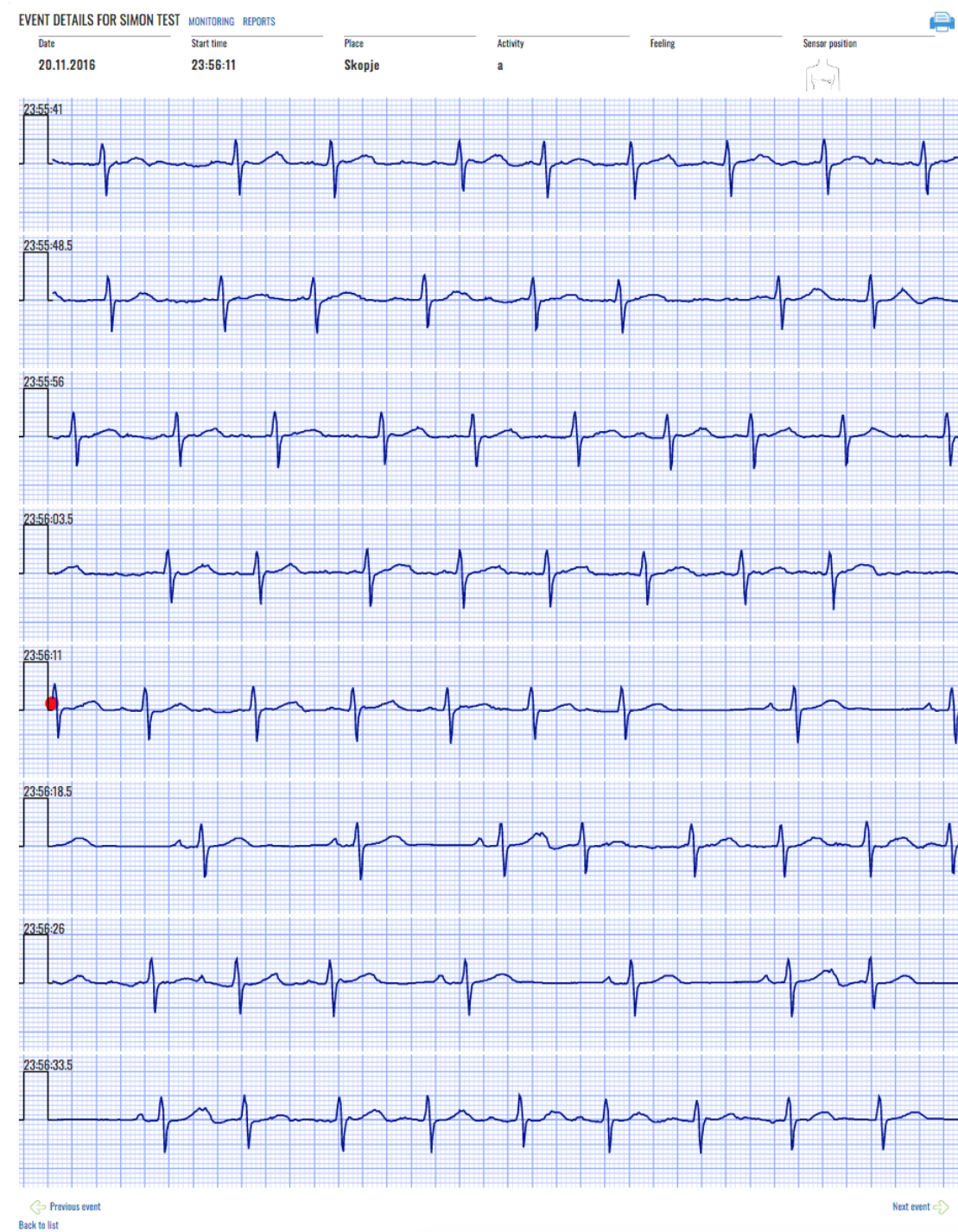


Figure 18: A sample of recorded event.

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

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According to the event time duration marking, the display may contain 8 rows of ECG strips for a 60 seconds event, 12 rows for a 90 sec event, or 16 rows for a 120 sec event. Furthermore, 8 rows fit in one page, and 16 rows fit in two pages.

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

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

Printing an event

The events details page contains a “Printer icon”. A click on “Printer icon” invokes a dialog form to print the event (Figure 19).

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

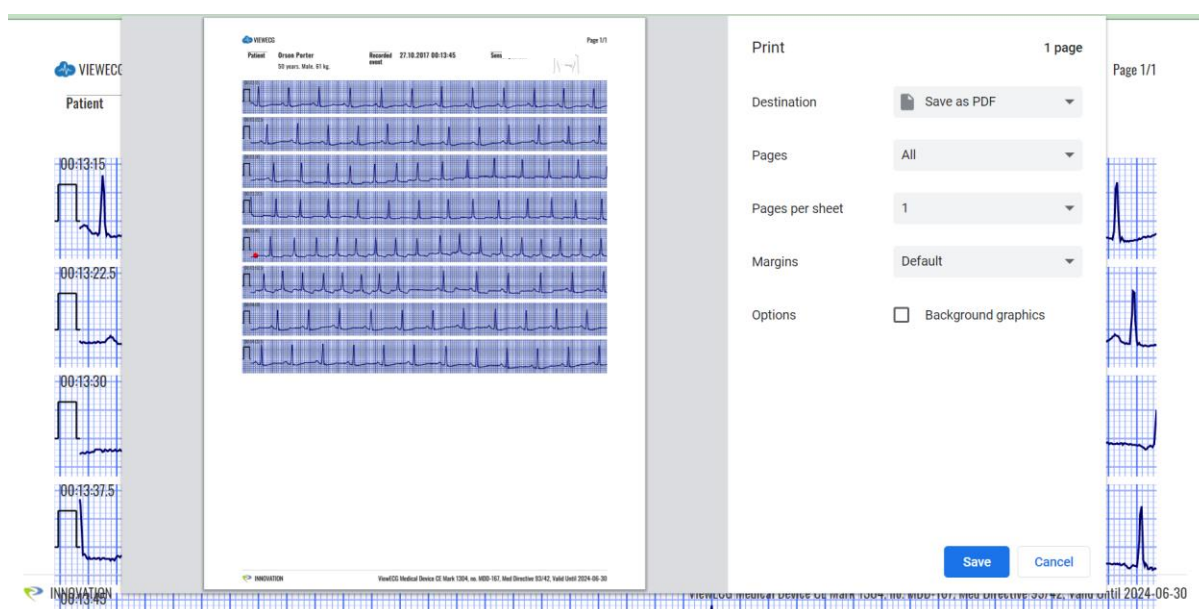


Figure 19: Dialog form to print an event.

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

Event in Monitoring view

An event is marked in the “BPM, Beats, Episodes and Events navigator” with yellow triangle figure positioned on the upper side for an event (Figure 20). Hovering over the triangle figure, info window will show listing the exact time of event occurrence and activity description.

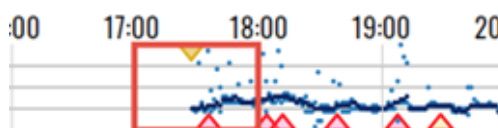


Figure 20: Events in BPM, Beats or Episodes navigator.

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An event is marked in the “List of ECG strips” with a yellow diamond shape figure positioned in the ECG strip where the event occurred (Figure 21). Hovering over the figure, info window will show listing the exact time of event occurrence and activity description.

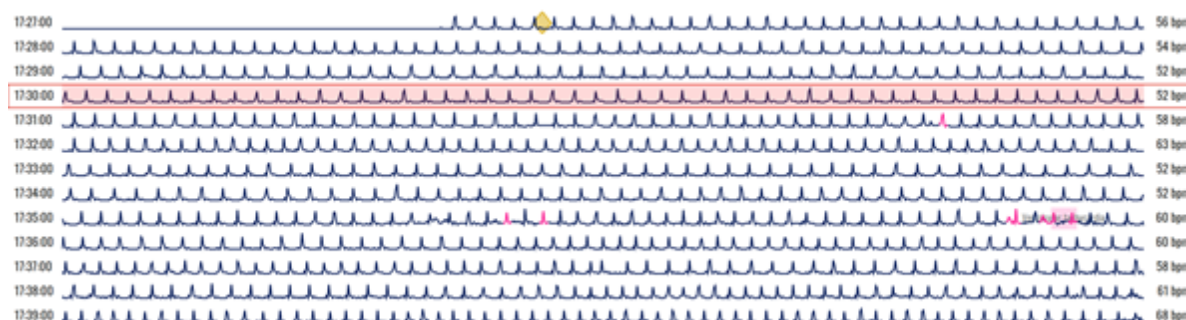


Figure 21: Event in List of ECG strips.

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

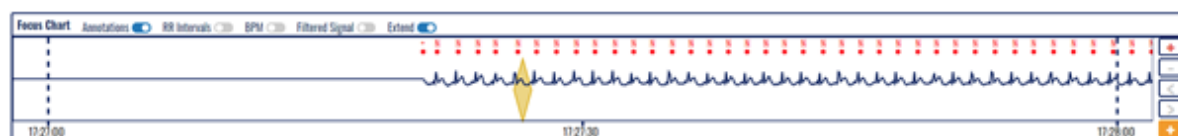


Figure 22: Event in Focus chart.

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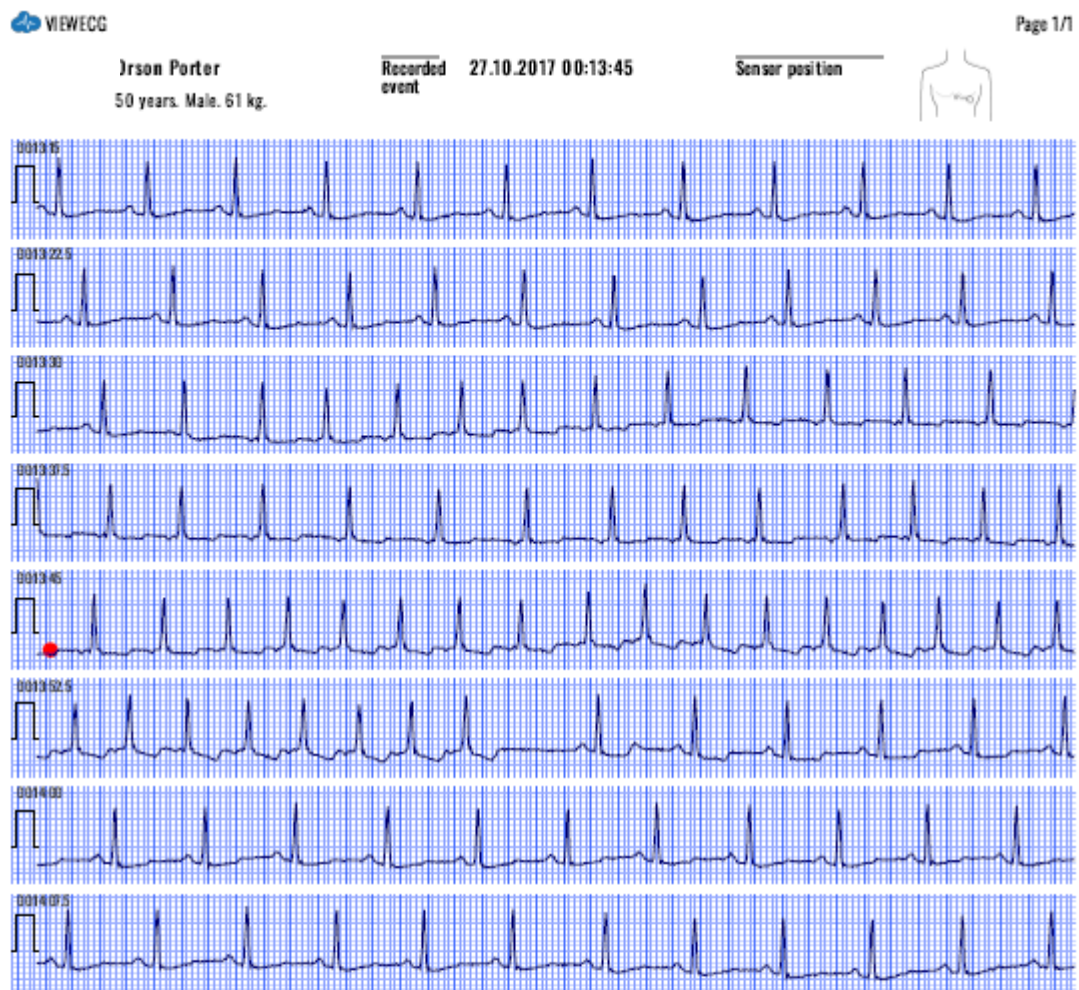


Figure 23: A pdf corresponding for recorded event.

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4.4. Thresholds

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

Profiles

When the profile link is activated then the profiles page is opened, as presented in Figure 24. The list of patient profiles is displayed by their names, followed by a check box to select if it is 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 pr 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 24: Profiles page.

The button with active link “Create new” is used to create a new profile. If clicked, then the form to create a profile is presented in Figure 25. You can enter the name of the new profile 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 to create a profile.

Create Alert Profile

Name

Is Default

☐

[Back](#)

Figure 25: Create a new profile form.

Edit Alert Profile

Name

Is Default

☐

[Back](#)

Figure 26: Edit a profile.

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The created profile can be edited if the corresponding link is selected next to the selected profile in the list of profiles. Then an edit form for a selected profile is shown in Figure 26. To finalize the editing click the “Save” button or select “Back” to cancel the editing operation.

Rules

The list of predefined alert rules that can be imported in a profile by a form in Figure 27.

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 27: Import profile rules.

The list of thresholds and alert rules for a selected profile is shown in Figure 28.

Profile Rules - Athlete

[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)	10 sec.		40	Edit Delete

[Back](#)

Figure 28: 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 by a form presented in Figure 29. 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 29: Edit an alert rule.

An alert rule can be deleted by clicking on the delete link. A confirmation form for deletion is presented in Figure 30. 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 30: Delete an alert rule.

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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 31.

Figure 31: Create an alert rule for a rhythm episode.

The risk level can be selected among three different values as LOW, MEDIUM, and HIGH, as presented in Figure 32.

Figure 32: Select a risk level to be raised.

The list of possible rhythm episodes to be selected to set a threshold value for an alert rule is presented in Figure 33.

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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)
- BII (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 33: Select a rhythm episode for the alert rule.

Clicking the “Create Beat Rule” button on the list of rules will activate a form to create an alert rule specifying thresholds for a heartbeat type is presented in Figure 34.

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 34: Create an alert rule for a heartbeat type.

Clicking the “Create QT Rule” button on the list of rules will activate a form to create an alert rule specifying thresholds for a QT interval type is presented in Figure 35.

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 milliseconds

If QTc Bazett is greater than milliseconds

If QTc Fridericia is less than milliseconds

If QTc Fridericia is greater than milliseconds

If QTc Framingham is less than milliseconds

If QTc Framingham is greater than milliseconds

Active ☒

[Back to list](#)

[Create](#)

Figure 35: 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 is presented in Figure 36.

Create Alert Rule - Athlete

Pause with risk level Select Risk Level

if minimum duration is seconds

Active ☒

[Back to list](#)

[Create](#)

Figure 36: 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 accompanied to a patient on the doctor’s home page or by clicking the monitor menu option when the doctor accesses the events or reports of a patient.

5.1. Main monitoring page

Page overview

When the monitoring tools are invoked, the system displays the main monitoring page (Figure 37).

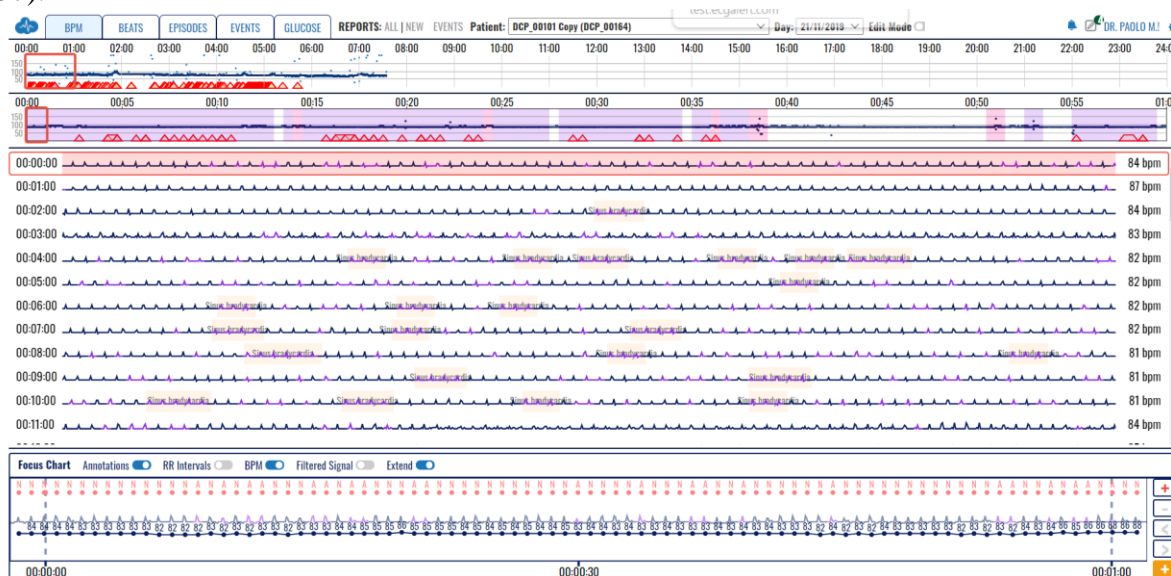


Figure 37: Main monitoring page.

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

Basic functions

The basic 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 38) is made up of four main sections:

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

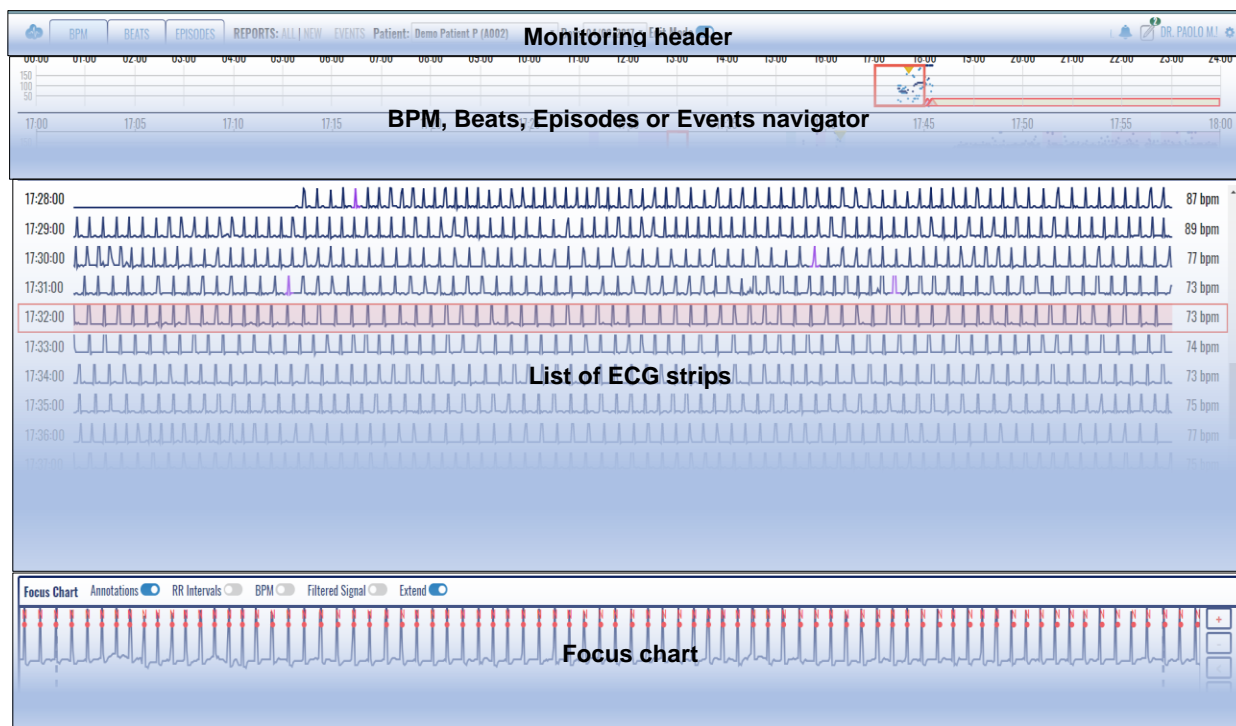


Figure 38: Main graphical sections.

The left part of the monitoring header contains links to most used functions and menu options, including toggle switch between bpm, beats, episodes and events information for easier 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, doctor name and settings drop-down menu.

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

A list of ECG strips is displayed in the third section, along with information about calculated average BPM for each given strip.

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

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5.2. Monitoring header

The monitoring header replaces the standard web application header. It displays additional features and functionalities besides those in the standard application header.

Home icon

By clicking the “ViewECG icon” in the top leftmost corner (Figure 39), the user is redirected to the doctor's home page.



Figure 39: ViewECG icon is acting as home page link.

Choose a patient

By clicking the “Patient's name” (Figure 40), 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 40: Choose a patient for monitoring.

Choose a date

By clicking on the “Date” (Figure 41), a drop-down list appears displaying all days a patient has realized measurements. By changing the selected list item, the doctor is redirected to the newly selected day record.



Figure 41: Choose a date for monitoring.

Edit mode

By clicking on the “Edit mode” switch (Figure 42), you can toggle between the option to edit the automatic diagnosis provided by the software or manually add new episodes of arrhythmias.



Figure 42: Edit mode toggle switch

System notifications

The “Alarm icon” (Figure 4) 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, events to display critical moments when the patient marked the recording.

Reports

The “All” link (Figure 43) from the reports label is used to display a list of completed reports for the selected patient and the “New” link displayed next to it is used to go 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 43: Link to completed reports (electronic health record) for the selected patient.

Events

The “Events” link (Figure 44) leads to a list of the events, the patient has specified while wearing the wireless sensor.



Figure 44: Link to events for the selected patient.

All draft reports

The “Draft reports” icon, located next to the alarm icon (Figure 45) is used to display the list of draft reports for all patients. The indicating number shows how many drafts the doctor has started and not completed yet. In case there are no draft reports, the draft report icon will not be displayed.



Figure 45: One draft report notification.

Username and settings

The username and settings icon found at the top most right corner (Figure 46) are used to log OFF, change user profile information, or setup the settings for monitoring tools.



Figure 46: Settings option.

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Monitoring Settings

The monitoring settings menu (Figure 47) 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 either to count or duration.

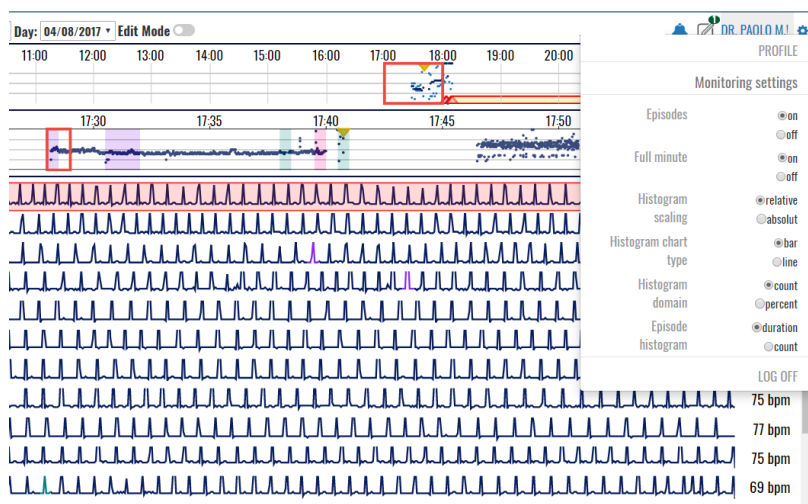


Figure 47: Settings page of the monitoring page.

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5.4. BPM navigator

The selector toggle switch enables to select the navigator type (bpm, beats, episodes and events). In a case the bpm navigator is selected, two navigators are displayed: the hour navigator and ECG strip selector. The heart rate navigator enables visualization of heart rate over a given time frame and easy navigation. It contains information on 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 48) is divided into 24 subsections, each corresponding to one hour within the day. Time indicators clearly display the hours. Only the realized measurements are displayed, and the missing parts are empty.

A red rectangle surrounding one of the hourly sections is used as an indicator for the current hour on display. By default, the red rectangle is set to the first hour of realized measurement during the day.

By clicking one of the sections, the hour context is changed in accordance with the clicked section, and therefore, this navigator acts as a selector of a corresponding hour to be displayed.

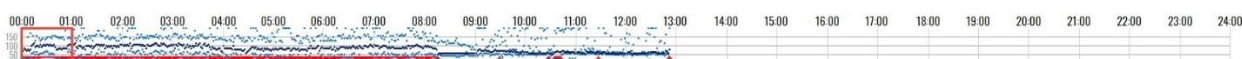


Figure 48: Hour selector.

The hour navigator (selector) represents a heart rate chart. Each displayed pixel corresponds to a certain 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.

There are three horizontal lines spanning throughout the hour selector corresponding to a heart rate 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. In the case a point on the chart exceeds the interval, it will be displayed as a 200 BPM value.

There are indicators for detected episodes 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 detected rhythm episode. In a case there is a detected episode, the mouse over shows a popup tooltip, which contains information for all the episodes present in the particular hour segment. The provided information comprises of 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 49) displays a 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 ECG strips with a duration of a half or full minute via the monitoring settings section in the Settings page.

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

There are time indicators on the ECG strip selector, that is, a time indicator for each 5 minutes' interval.

A red rectangle surrounding one of the ECG strip selector sections is used as an indicator for the current displayed interval. By clicking on a location of interest, this interval context is changed in accordance with the clicked section.

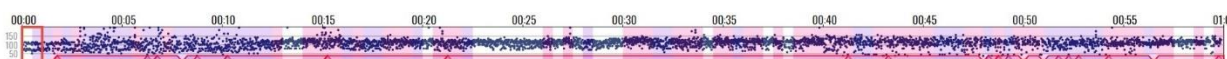


Figure 49: ECG strip selector.

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 drawn in dark navy color.

There are three horizontal lines spanning throughout 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. In the case 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 with a popup tooltip that contains information. This information comprises of a time stamp of the episode start, its rhythm identification and the duration for every episode present in the selected segment.

The background of each ECG strip section representation is colored in accordance 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.

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5.5. List of ECG strips

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

Displaying the list

The list of ECG strips (Figure 50, Figure 51) contains a list of 120 ECG strips with duration of 30s or a list of 60 ECG strips with duration of 60s, in accordance with the chosen setting.

ECG strips are presented in each row of the list. The information of the start of the ECG strip is indicated on the left, and the average heart rate on the right. Empty strips display "NaN" instead.

The displayed ECG strip is not the actual ECG signal, but a signal that is filtered using a band-pass filter in the range [0.5Hz, 30Hz] with filter length of 0.2s to eliminate the baseline drift or high frequency noise. Therefore, it is expected that the displayed strip is somehow modified version of the original recording, but an experienced doctor can notify all related arrhythmia on this signal easier than on the original recording. The focus chart is used to analyse the original signal and determine its features. These ECG strips are just fast indication for faster analysis.

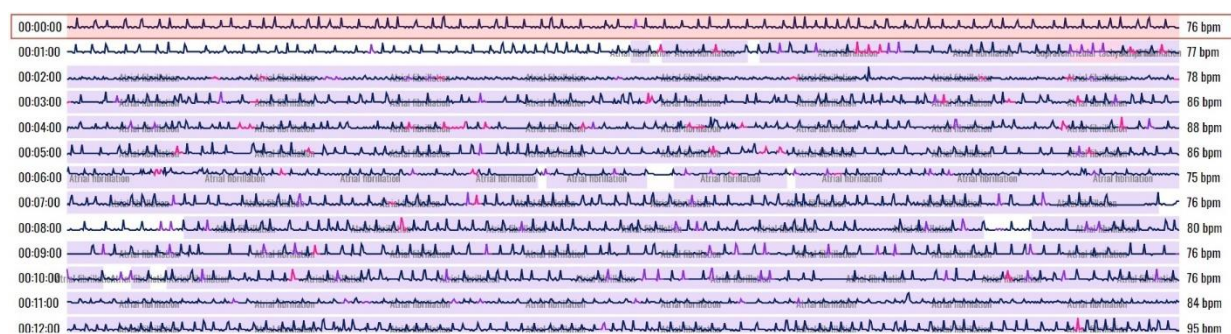


Figure 50: List of ECG strips.

One ECG strip is indicated by a red bordered rectangle around the line (Figure 51). 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 indicated 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 rhythm 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 with selecting this ECG strip, move the colored red square around it and display 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 size (2x). A consecutive

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double click will display a smaller ECG segment with doubled size (4x), and another click even the 8x magnification size.

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 be used to move the visible part of displayed ECG strips.

The vertical navigation is also possible by mouse scroll functions, so the list can be scrolled upwards or downwards.

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

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

By double clicking a certain location on the ECG strip, the magnification level increases on the focus chart and the position indicator adjust its position and size in accordance with the new magnification level. The process can be repeated until the maximum magnification level of 8 is reached. In the case of magnification, the position indicator (Figure 51) can be dragged towards left or right so that the focus chart horizontal offset is adjusted.

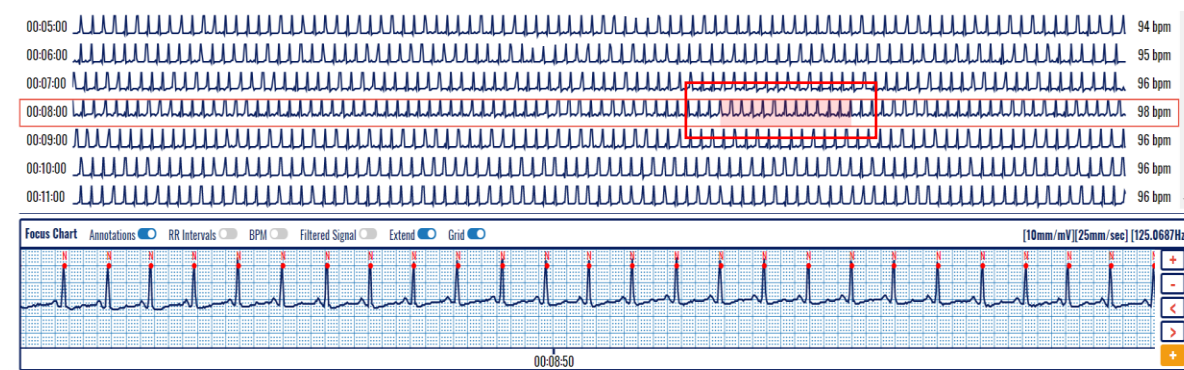


Figure 51: An ECG strip with selected segment to be displayed in the focus chart.

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5.6. Focus chart

The selected ECG strip from the displayed list is presented in greater details in the Focus chart (Figure 52). 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 53).

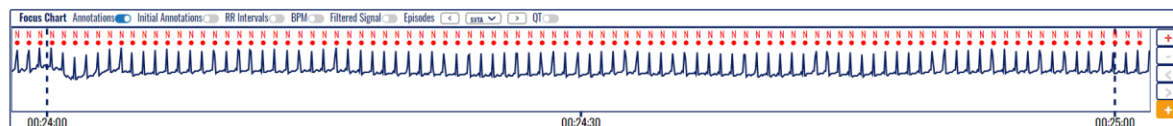


Figure 52: Focus chart.

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

All detected beat types are indicated in the ECG strip by a corresponding annotation color (Figure 53). The normal beat annotations are not marked or indicated on the ECG strip.

A semi-transparent colored rectangle on the focus chart maybe used to indicate a detected episode (Figure 53). Discretely, the title of rhythm the episode is written on the background of these rectangles behind the displayed ECG signal to avoid any misinterpretations.

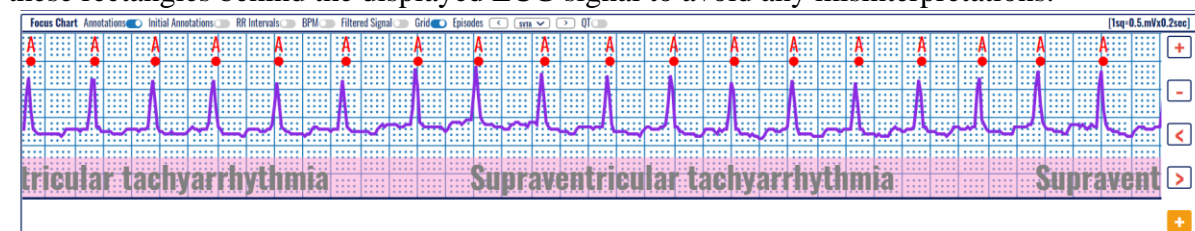


Figure 53: A focus chart with identified beats and rhythm episode.

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Magnification levels

There are four different levels of magnification:

- X1 – the focus chart visualization window fits to the entire ECG strip (Figure 54);
- X2 – the focus chart visualization window fits to half the length of the ECG strip (Figure 55);
- X4 – the focus chart visualization window fits to fourth of the length of the entire ECG strip (Figure 56); and
- X8 – the focus chart visualization window fits to eighth of the length of the entire ECG strip and the height of the focus chart is doubled for better visualization (Figure 57).

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

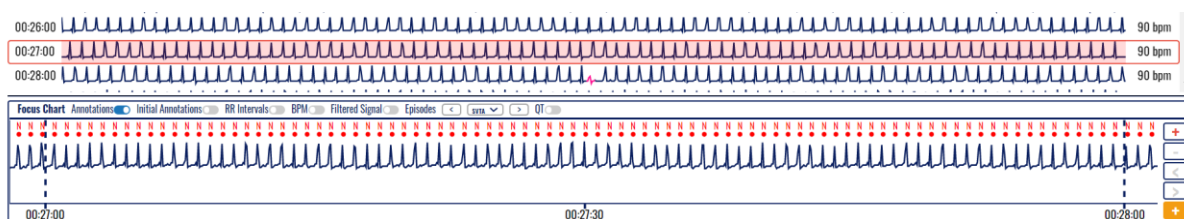


Figure 54: Selected ECG strip segment and focus chart presenting annotated beats.

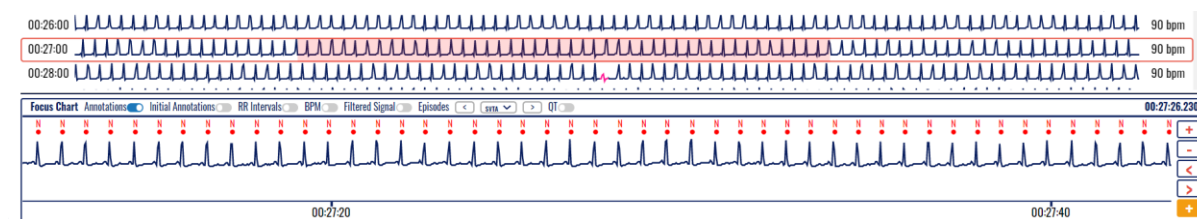


Figure 55: Selected ECG strip segment with 2x magnification and focus chart presenting annotated beats.

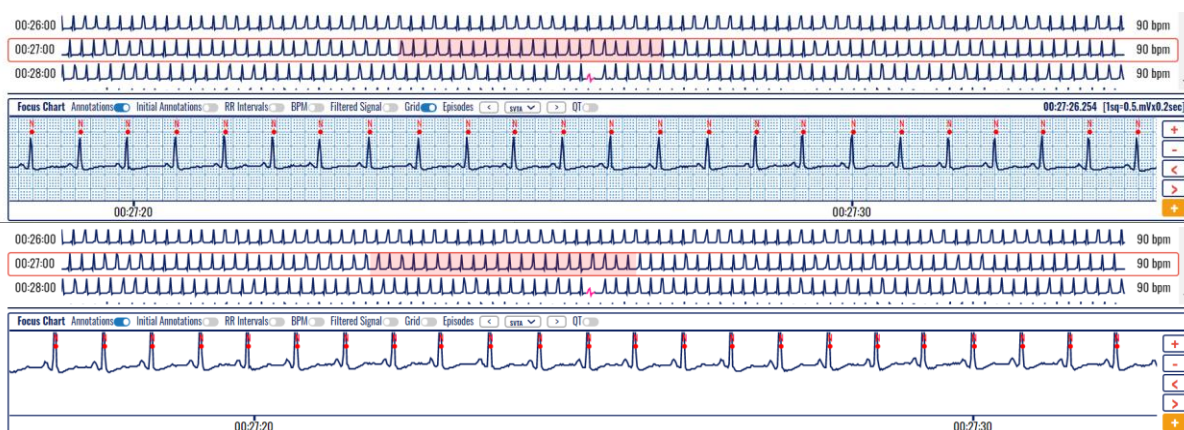


Figure 56: Selected ECG strip segment with 4x magnification and focus chart presenting annotated beats.

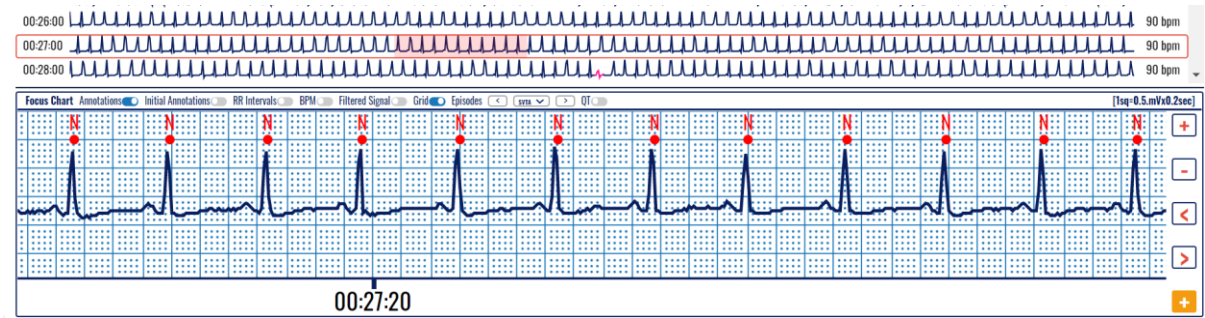


Figure 57: Selected ECG strip segment with 8x magnification and focus chart presenting annotated beats.

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 case of X4 or X8 magnification the time markings are drawn for each 5s in case of half minute ECG strip and for each 10s in case of 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 which 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. In the case 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 in from the Main Menu, the display of QTc values can be toggled between Bazett, Friderica and Framingham; and
- Episodes drop down menu – selects between the available episodes and navigates between the previous and next one.
- 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 heart beats (Figure 58, Figure 59, Figure 63 and Figure 64). When annotations are not displayed, then each detected heartbeat is marked only by a red dot (Figure 60, Figure 61 and Figure 62).

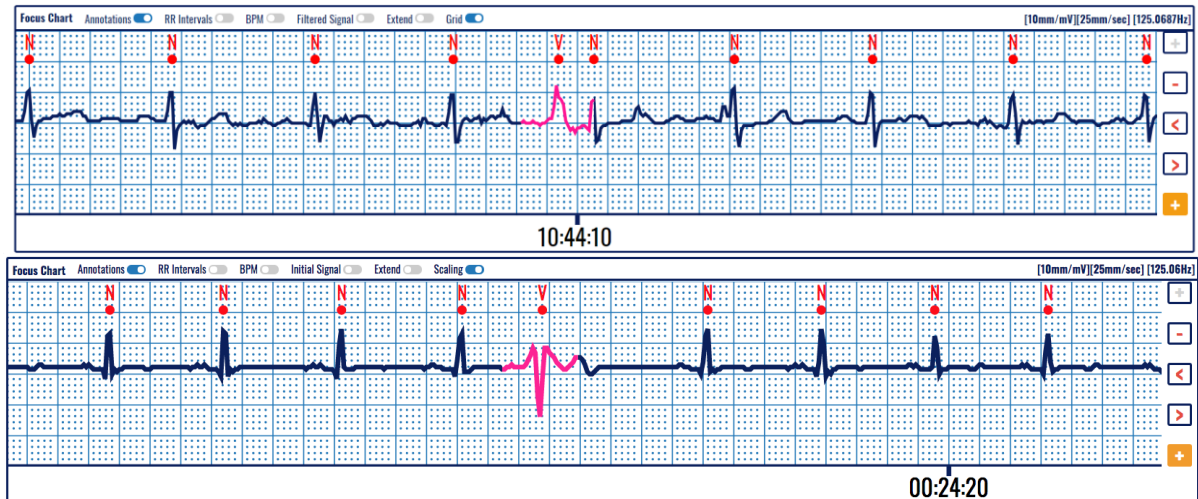


Figure 58: Focus chart presenting annotated beats of an ECG strip on a predefined grid.

Grid is usually used in ECG strips (Figure 58) for easier 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, then the displayed ECG (Figure 59) is scaled to the allowed height.

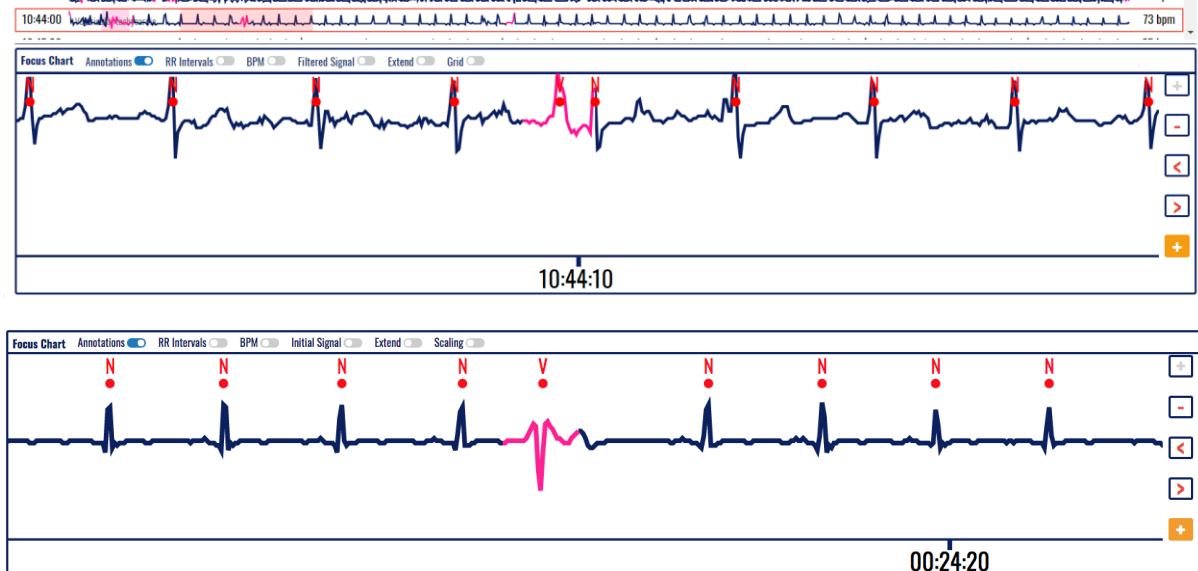


Figure 59: Focus chart of annotated ECG strip presented without grid.

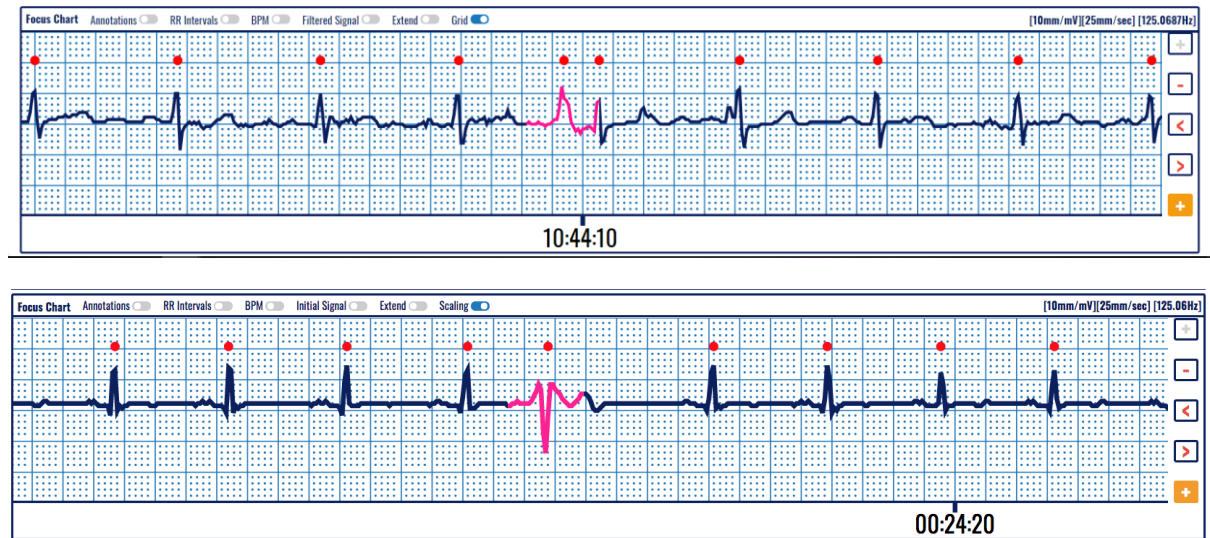


Figure 60: Focus chart presenting an ECG strip on a predefined grid.

Extended heart rate-related info

When corresponding toggle switch is activated, then the RR intervals are displayed in seconds (Figure 61) to represent distances between detected consecutive heartbeats.

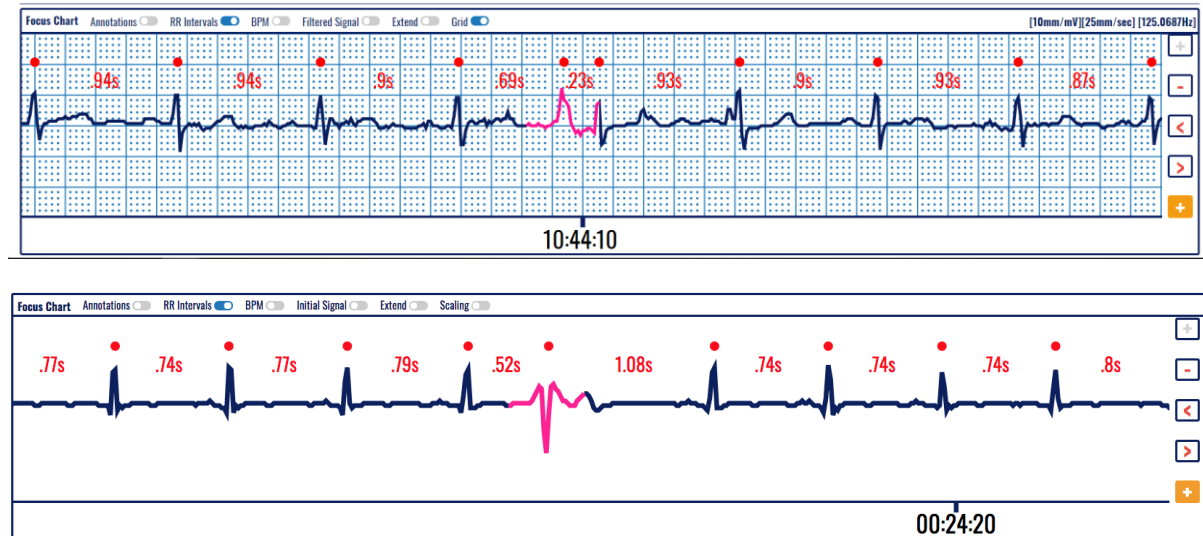


Figure 61: Focus chart without annotations including the RR intervals.

The toggle switch on BPM results with a display of a heart rate chart corresponding to each detected heartbeat. This will show current changes of the heart rate (Figure 62).

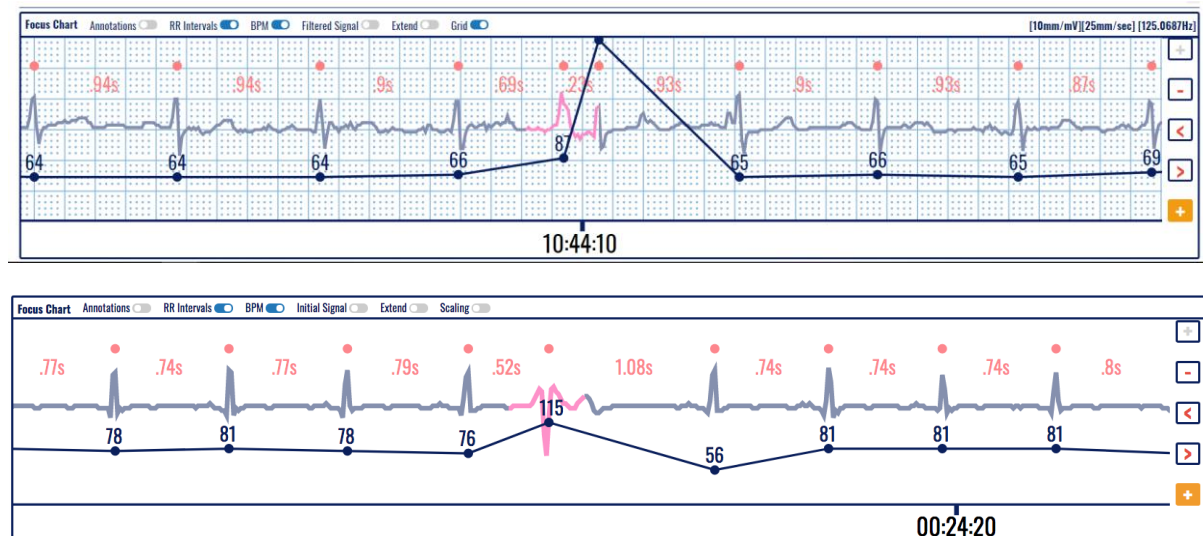


Figure 62: Heart rate information along with RR intervals on the focus chart.

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Extended visualization features

The filtered ECG recording (Figure 63) is displayed when corresponding toggle switch is activated. It is displayed on top of the original signal and can be used for easier identification of the beat type or rhythm episode analysis.

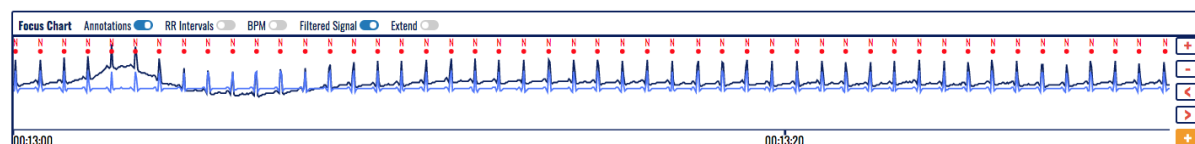


Figure 63: Filtered ECG recording presented on top of the annotated original signal with RR intervals.

Sometimes, a beat may occur in the very beginning or ending of the ECG strip, and therefore, it is very difficult to analyze it in a broader context. The extend feature (Figure 64) allows extension of the visible part, so even this beat can be analyzed in context of previous or next heart beats. It is activated or deactivated by the corresponding toggle switch.

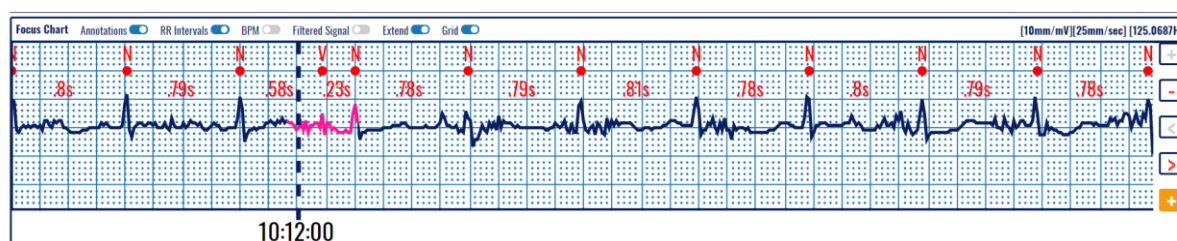


Figure 64: Extend segment function used on focus chart on a predefined grid.

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Magnification and navigation

On the right side of the ECG strip in the focus chart, there are four control buttons that 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 segment to report (+) on orange background – used for reporting purpose.

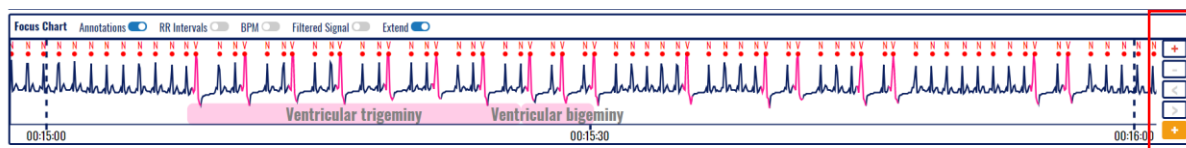


Figure 65: An extended display of the ECG in the focus chart (1 sec out of 30 sec borders).

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 which are 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 title of the episode 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 so that it corresponds to the magnification level of the focus chart. In the case the magnification level is X4 or X8 and the scaling is turned on, the ECG grid mesh is drawn behind the ECG signal and "[1sq=0.5mV x 0.2sec]" marking appears on the far right corner of the focus chart section header.

In a case of magnification level greater than X1, the focus chart can be dragged towards 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 strip changes its horizontal offset so that it corresponds to the horizontal offset of the focus chart.

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

Below the assistive navigation buttons there is another button marked with (+) in orange background so that it differs from the other assistive navigation buttons. It is used to add an ECG strip with a duration of 7.5s 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 66. The background will be colored in green if the calculated QTc value according to the Bazett formula results with a QT interval in a normal range, or in an orange background if it is longer or shorter than the normal range.

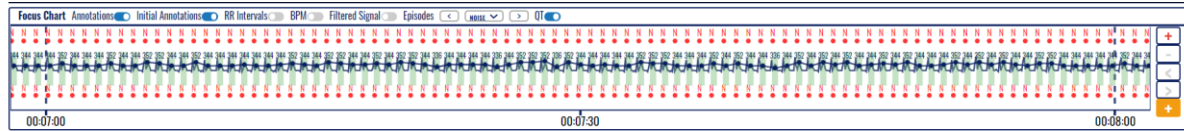


Figure 66: QT in Focus Chart.

Figure 67 presents zoomed portion of the Focus chart with displayed QT intervals. Note that the software might detect noise such in the second QRS and will not calculate the QT interval (the negative pick after the T-wave corrupts the signal and proper identification of the end of the T-wave). The other QT intervals are properly 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 correspondingly.

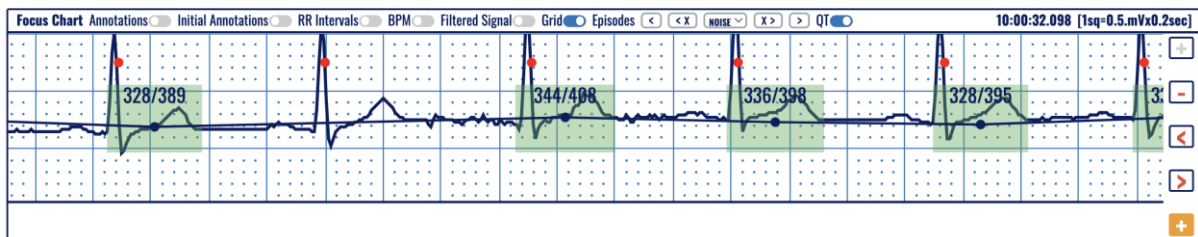


Figure 67: Detection of normal QT intervals (green background) in the Focus Chart.

Detection of QT intervals out of the normal range are displayed in orange background. For example, Figure 68 presents a long QT interval calculated according to the Bazett formula (measured QT is 520 and calculated QTc is 486).

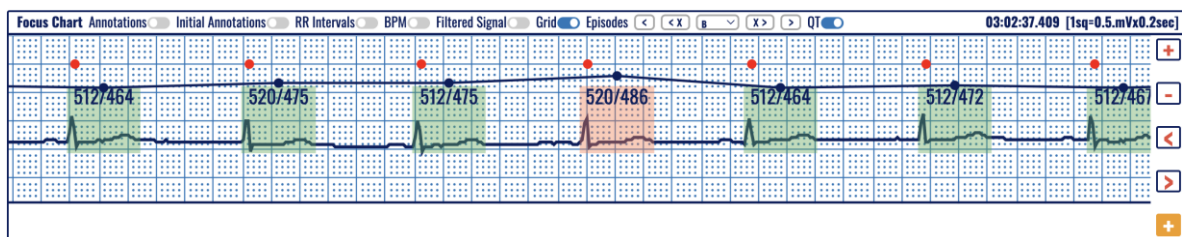


Figure 68: Detection of a long QT interval (orange background) in the Focus Chart.

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5.7. Edit mode

The edit mode is toggled with a click on the “Edit mode” toggle switch in the monitoring header section (Figure 42).

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

There are no visual changes in the list of ECG strips or the focus chart when the toggle switch is enabled, but the user can edit the list of ECG strips by using drag and drop actions.

When a doctor clicks and holds the left mouse click over a strip in the List of ECG strips section, the drag and drop function is activated. Then the user can drag the mouse to select the preferred area and when he drops the mouse click a dialog box appears (Figure 69). 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 69: Edit mode's drag and drop function dialog box

If the user makes a change to the annotations of the ECG records and then toggles the Edit mode button to disable it there appears an annotation changed prompt window that informs the user that the changes in the annotations have been successfully processed (Figure 70).

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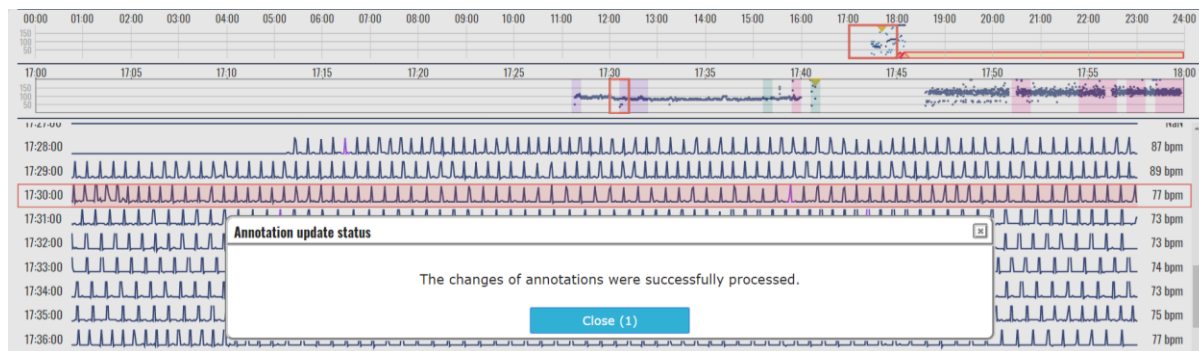


Figure 70: Annotation update status prompt

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

Upon clicking the edit episode menu item, a dialog window opens that looks like the one described in Figure 69 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 and if the user doesn't want to save the changes, he can abort the action by clicking on the Cancel button.

Upon click on the delete episode menu item from the right click context episode menu, a confirmation window opens to the user, asking him 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 these section cannot be accessed while the Edit mode is on. A confirmation dialog window is displayed with a question to save the changes made during in Edit mode, or to cancel the changes. Clicking on "Continue" will exit the Edit mode and continue to the Beats or Episodes sections, and clicking the "Cancel" will continue to stay in the BPM section with enabled Editing mode (Figure 71).



Figure 71: Leaving Monitoring section when Edit mode is enabled prompt window

When the doctor tries to enter into Edit mode and Beats or Episodes section is selected in the navigation from the monitoring header, the system displays a dialog box prompting the user that the Edit mode is unavailable from the selected section and if he wishes to continue to edit mode, he has to exit the current section (Figure 79).

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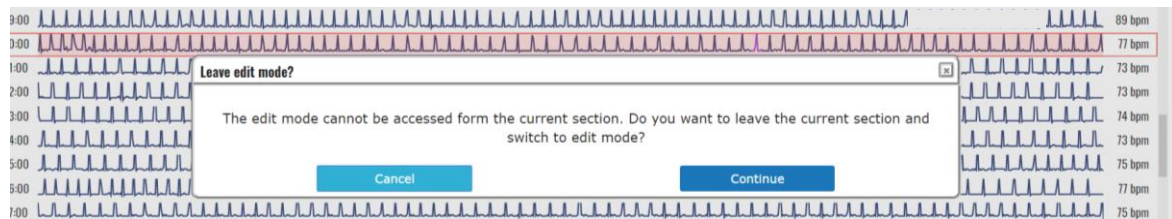


Figure 72: Prompt when a user tries to enter Edit mode from Beats or Episodes section

The edit mode supports a 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 works while having the Shift button pressed down (Figure 73 and Figure 74). In case of leaving the page without exiting the edit mode, the doctor will be automatically prompted by pop-up window for attempting to leave the monitoring page without saving the changes.

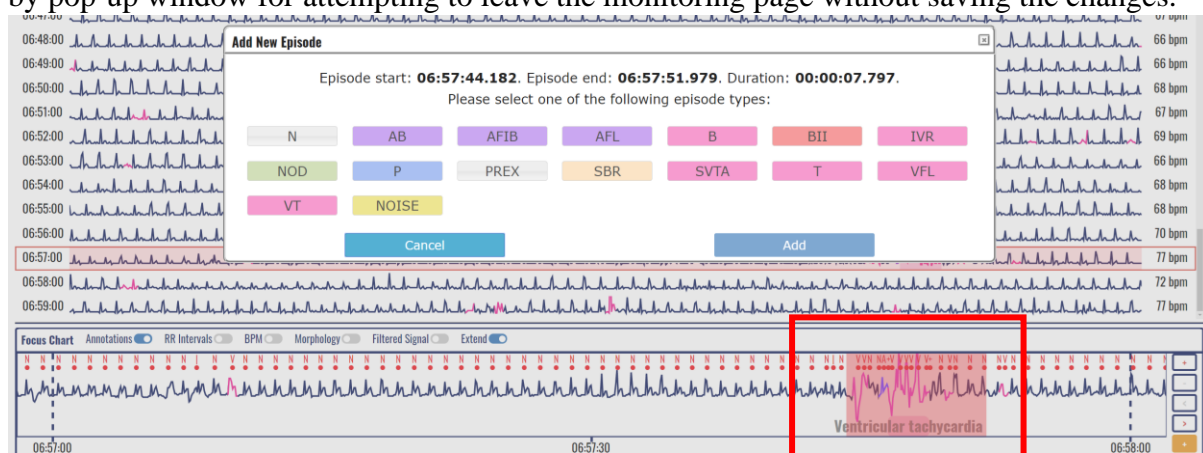


Figure 73: Segment selection for segment editing



Figure 74: Segment selection with Shift function

The doctor can edit the beat annotations by opening the edit annotation pop-up window by simultaneous press of 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 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 slide horizontally the content of the pop-up window by drag&drop interaction of the window content by clicking on anything but the annotations in the window (Figure 75).

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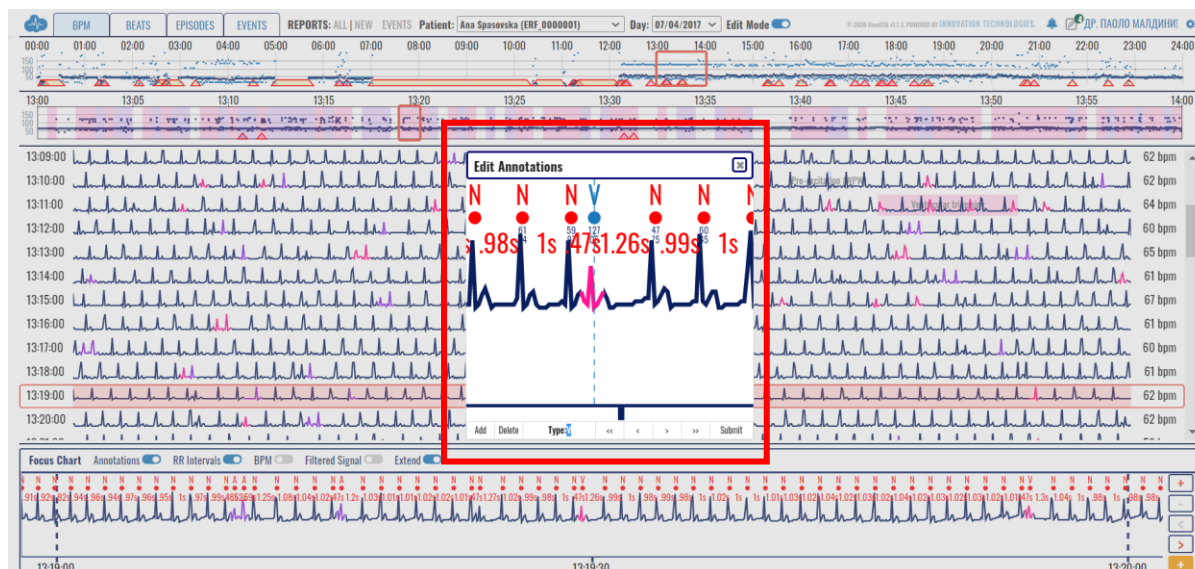


Figure 75: Beat annotation editing

The nearest annotation to the click is marked as 'selected', meaning that the changes will be applied to the selected annotation. The selected annotation is colored blue in contrast to the red annotations. The doctor cannot select '+' annotation, instead, the nearest non '+' will be selected. The exact positioning of the selected annotation is indicated with the help of 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 type 'N'.

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

Type – A textbox input control that changes the annotation type. If unsupported annotation is entered in the textbox, the user is prompted by 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 next annotation in the focus chart segment.

>> - Selects the next 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. By double click on the selected annotation, the annotation is either re-positioned exactly in-between the neighbouring annotations or is deleted (the decision to re-position or delete is AI supported for achieving optimal editing).

By double-click on anything but the beat annotations in the case there are missing beats in the corresponding RR interval at the double click position, the beats will be automatically added (AI assisted feature).

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To assist with optimal positioning of the annotations, there is BPM preview for the current annotation and the neighbouring four annotations (Figure 76). When the selected annotation is in optimal position (the neighbouring RR intervals result in BPM difference of ≤ 3 BPM) the BPM preview values are coloured green and are bolded, in contrast to the default blue colour of the BPM preview.

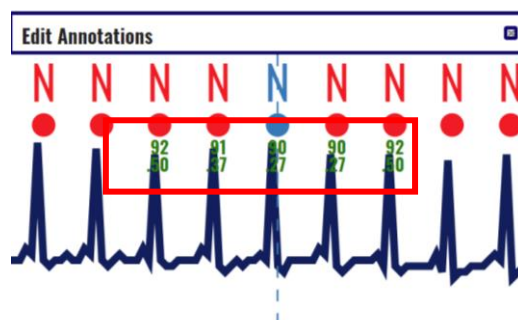


Figure 76: BPM preview

After submitting the annotation changes, the edit annotation window stays open for further editing. The user can close the window either by pressing the Esc button or by 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 on a click of the toggle buttons between bpm, beats, episodes, events, QT and alerts in the monitoring header section.

The role of the Beats (Figure 77) is to provide quick access to information on detected beat types for a particular period, and to navigate through appearances of detected arrhythmia beats. An additional visualization and monitoring tools is provided for detailed analysis of the detected arrhythmia.

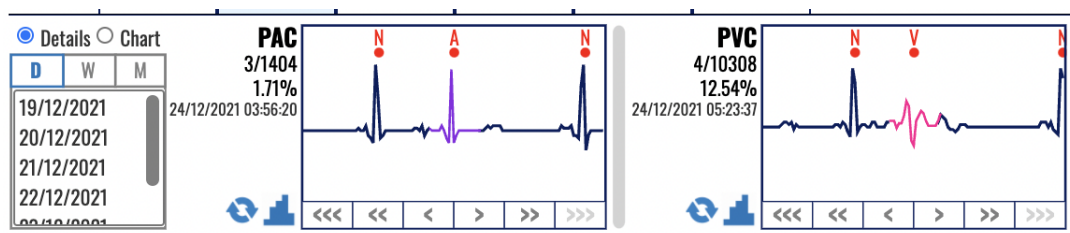


Figure 77: Beats navigator displayed instead of hour selector over the list of ECG strips.

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 which 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 time period and information domain.

The control section (Figure 78) 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.

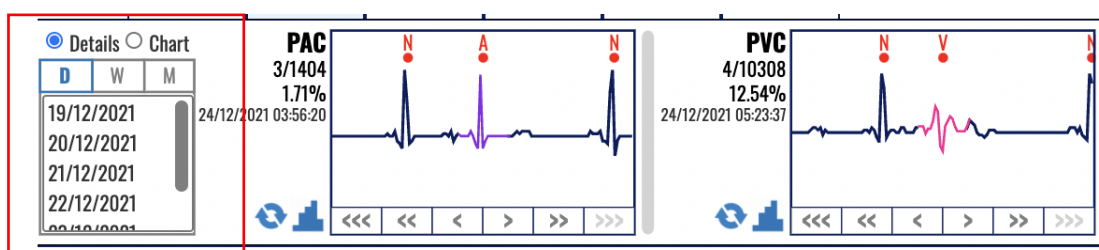


Figure 78: Control section of beats navigator.

The period selector section (left side of control section Figure 78) has a header on the top and a list of date ranges. If there are more dates than those displayed in the list, then there is vertical navigation bar for navigating 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 given time. The presented summary information in the content section corresponds to the period selected by this toggle switch.

The list of dates contains available periods with duration in accordance with 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 beats navigator displays the dashboard of annotated beats (Figure 79) and when the option “Chart” is selected the content section presents the annotation histograms of detected beat types (Figure 80).

The content section of the beats located on the right side of the beats navigator (Figure 79) provides statistical info and quick access to the selected information domain (beat annotations) for a time period selected from the beats control panel.

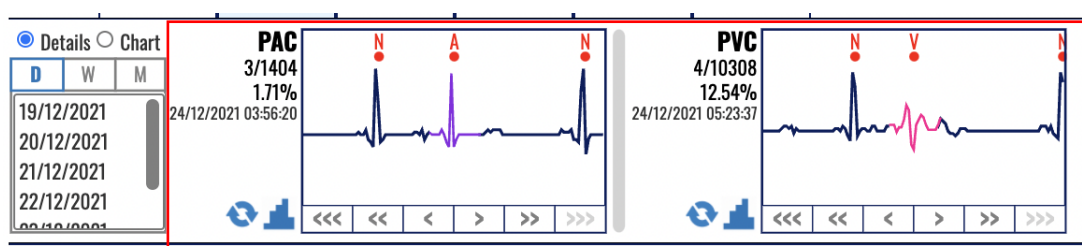


Figure 79: Content section of beats navigator representing dashboard of annotated beats.

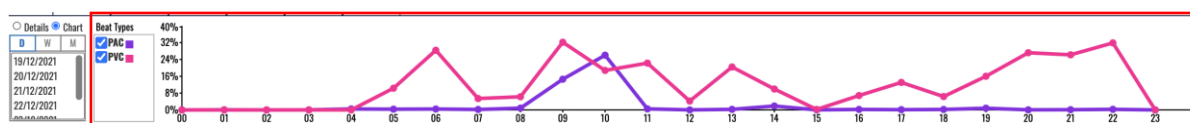


Figure 80: Content section of beats navigator representing annotation histograms.

Dashboard of annotated beats

This dashboard displays the annotated beats (Figure 79). When the information domain is set to details, the content section provides information box (Figure 81) for each annotation detected in the selected period.

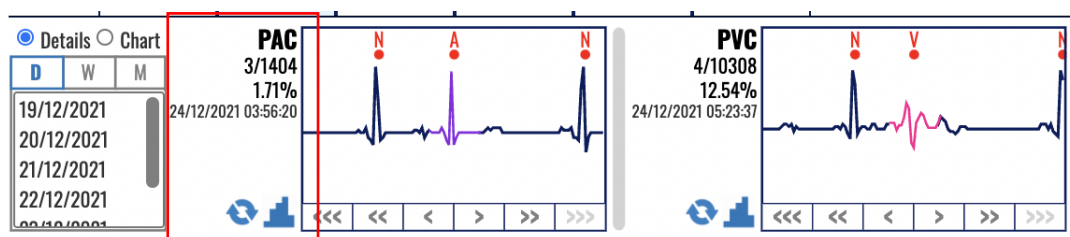


Figure 81: Information box is associated to each annotated beat type.

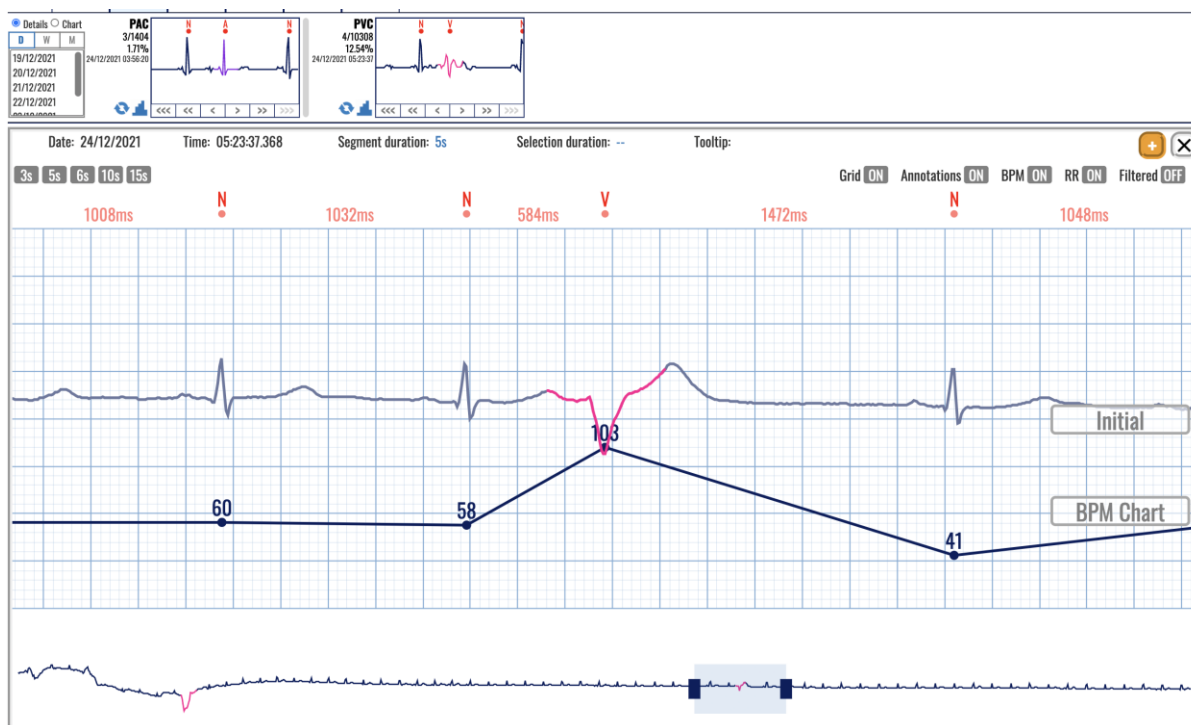
The information box contains:

- An abbreviated name of the annotation beat type that on mouse over displays a 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 heart beats (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
- Column chart icon which is shortcut to the corresponding annotation histogram column chart (shortcut for switching to annotation histogram context of the content section).

A click in one of the display boxes that represent the beat types will open the extended viewer in the main part instead of the list of ECG strips, as presented in Figure 82 to enable a better visualization of the detected arrhythmia beat.



• **Figure 82: 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 bellow the picture containing links:
 - Three left arrows (“<<<”) – displays an ECG recorded previous day (24h prior);
 - Two left arrows (“<<”) – displays an ECG recorded previous hour (1h prior);
 - One left arrow (“<”) – displays the previous recorded ECG (30 sec prior);
 - One right arrow (“>”) – displays the next recorded ECG (after 30 sec);
 - Two right arrows (“>>”) – displays an ECG recorded next hour (1h after); and
 - Three right arrows (“>>>”) – displays an ECG recorded next day (24h after).

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

The annotation abbreviation and the annotation display box have as tooltip information on 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.

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

Histogram of detected beat types

Beats navigator can present a histogram of annotated beats (Figure 83). The histogram shows the count of occurrences calculated per hour, so you can easily monitor when these detected beats occurred.

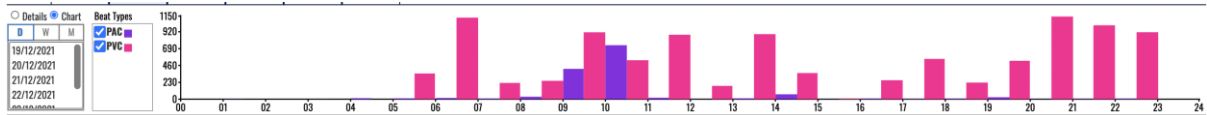


Figure 83: Column bar histogram of annotated beat types in the beats navigator.

A beat type selector (called series Figure 84) appears right of 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. A multiple beat type information can be showed within single column chart if more than one beat type is selected. By default, all beat types are selected.

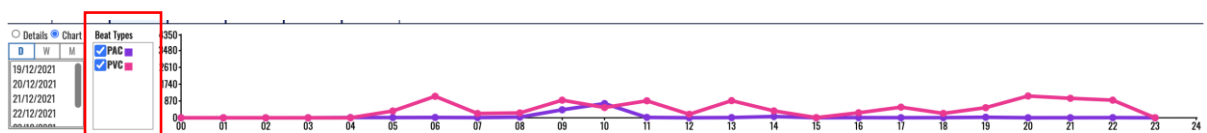


Figure 84: Beat type selector box for line-based histogram of annotated beats in beats navigator.

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, whilst the vertical, the number of occurrences of corresponding beat type in an hour.

The monitoring settings page (invoked by clicking the settings icon in the application header) can be used to setup other views of the histogram, such as line chart (Figure 84) instead of column bar chart (Figure 83). You can choose presentation of the histogram with relative percentages (Figure 85) instead of absolute values (Figure 83). Details on controls which toggle the histogram formatting can be found in the monitoring settings section.

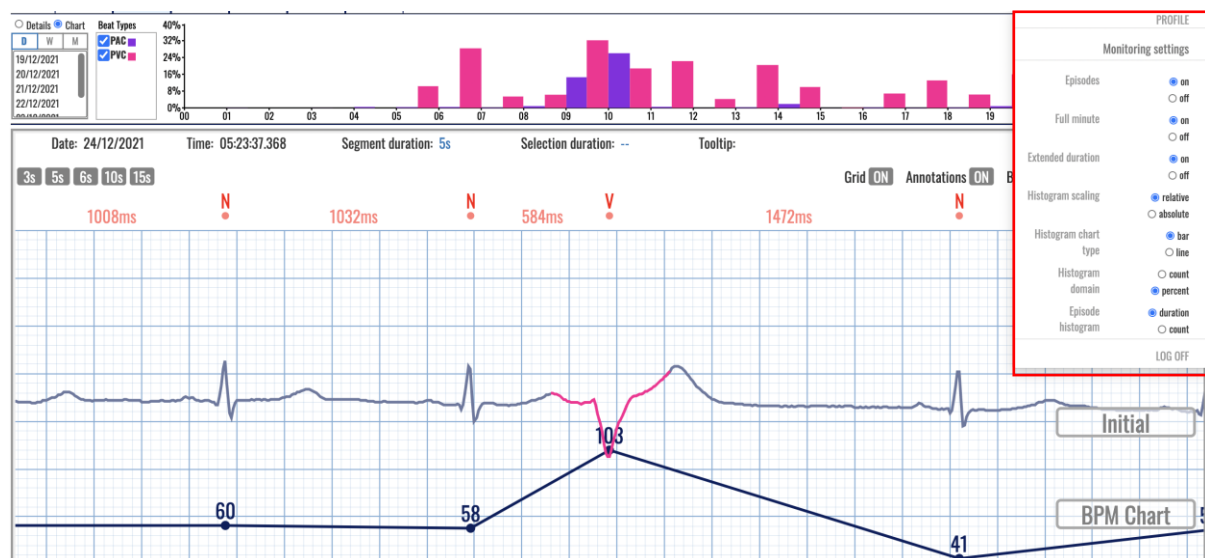


Figure 85: Histogram of detected beat types presented by lines instead of column bars.

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5.9. Episodes

The episodes navigator is toggled on a click of the toggle switch between bpm, beats, episodes, events, QT and alerts in the monitoring header section.

The role of the Episodes (Figure 86) 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.

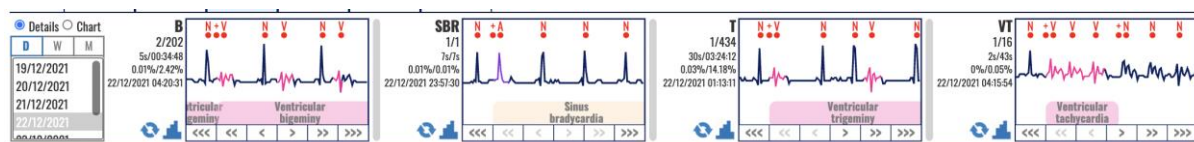


Figure 86: Episodes' navigator displays the detected arrhythmia episodes.

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

It is divided into two sections:

- Control section – located on the left of the dashboard; contains the controls which 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 time period and information domain.

The control section (Figure 87 and Figure 78) 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.

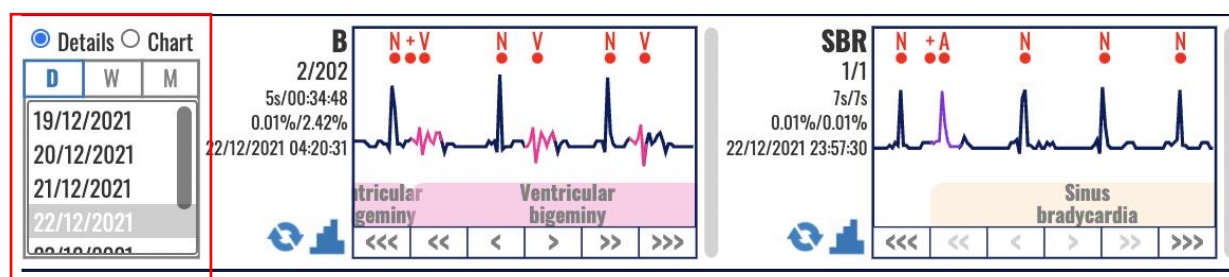


Figure 87: Control section of episodes navigator.

The period selector section (left side in control section Figure 87) has a header on the 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); and
- Month toggle (M).

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

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The list of dates contains available periods with duration in accordance with 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 88 and Figure 79) and when the option “Chart” is selected the content section presents the histograms of rhythm episodes (Figure 89).

The content section of the episodes located on the right side of the episodes navigator (Figure 88) provides statistical info and quick access to the selected information domain (episode annotations) for a time period selected from the episodes control panel.

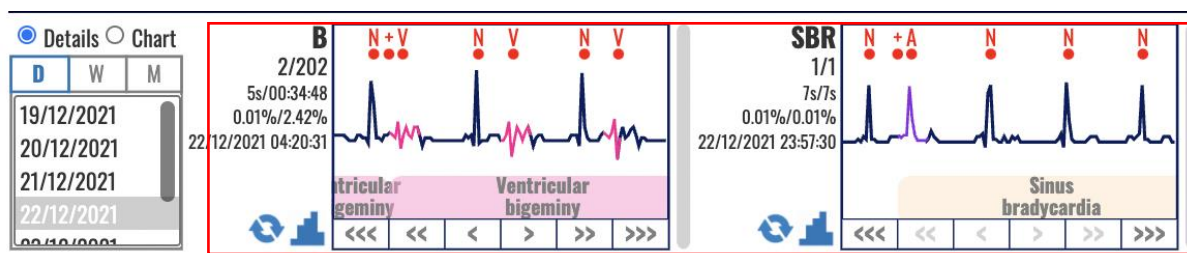


Figure 88: Content section of episodes navigator representing dashboard of annotated episodes.

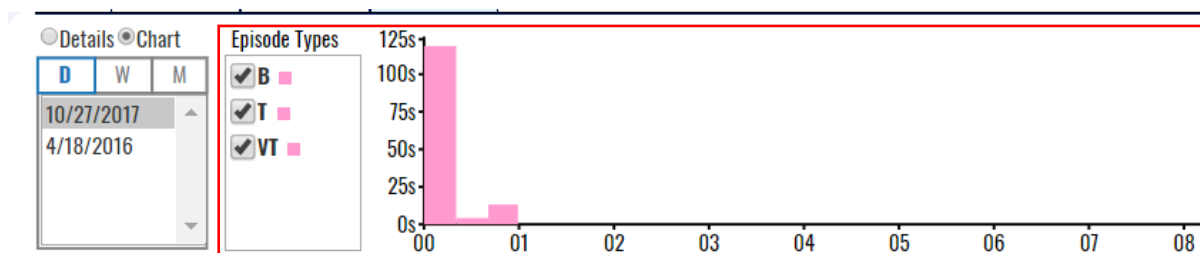


Figure 89: Content section of episodes navigator representing histogram of rhythm episodes.

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Dashboard of rhythm episodes

Dashboard can present detected rhythm episodes (Figure 90) by clicking on the corresponding radio button.

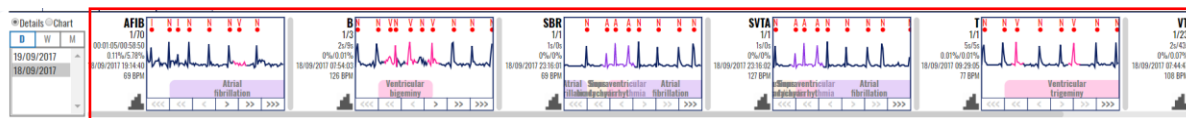


Figure 90: Dashboard of detected rhythm episodes.

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

The information box for detected rhythm episodes contains:

- An abbreviated name of the episode;
- Current identification and total number of rhythm episodes (the first number is the current episode identification and the second the total number of episodes);
- Duration of 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
- Column chart icon which is shortcut to the corresponding episode histogram column chart (shortcut for switching to episode histogram context of the content section).

A click on the displayed boxes that represent the detected beats will open the extended viewer (Figure 91) to enable better representation of the detected arrhythmia.

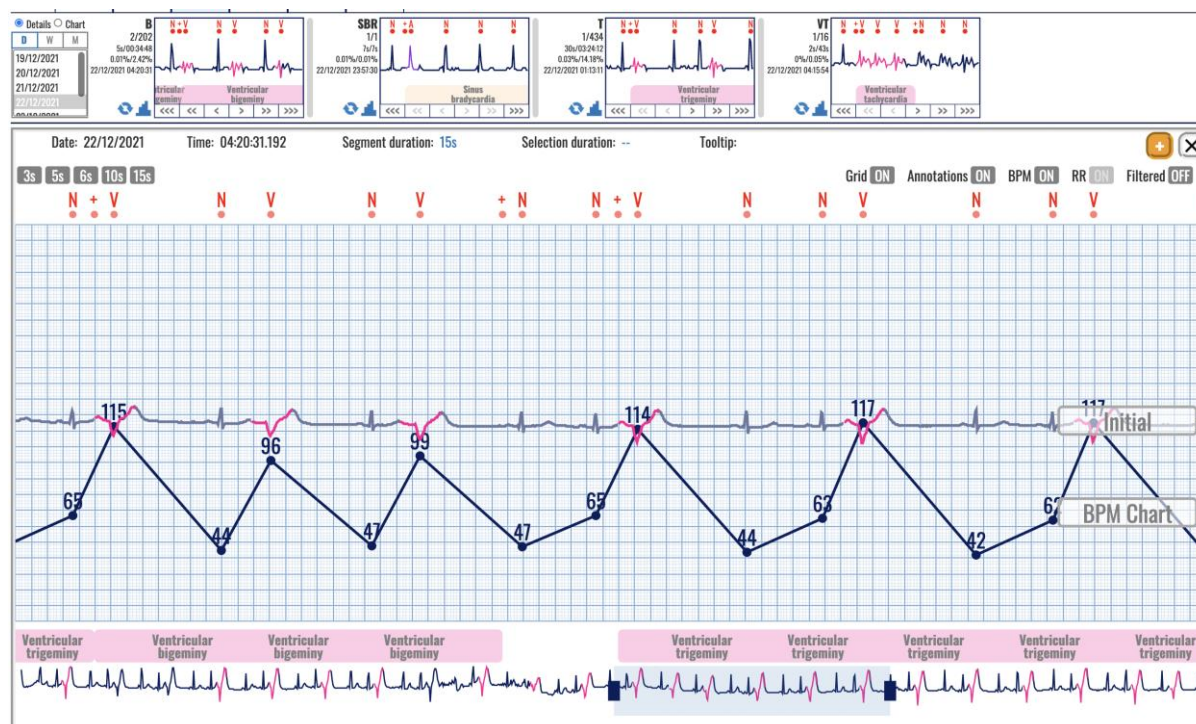


Figure 91: Detected rhythm episodes displayed in the extended viewer.

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 bellow the picture containing links:
 - Three left arrows (“<<<”) – displays an ECG recorded previous day (24h prior);
 - Two left arrows (“<<”) – displays an ECG recorded previous hour (1h prior);
 - One left arrow (“<”)– displays the previous recorded ECG (30 sec prior);
 - One right arrow (“>”) – displays the next recorded ECG (after 30 sec);
 - Two right arrows (“>>”) – displays an ECG recorded next hour (1h after); and
 - Three right arrows (“>>>”) – displays an ECG recorded next day (24h after).

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

A navigation button can be inactive in a case such an episode does not exist.

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

Histogram of rhythm episodes

Dashboard can display a histogram of detected rhythm episodes (Figure 92) by clicking on “Chart” radio button from the information domain selector.



Figure 92: Histogram of detected rhythm episodes.

A bar column view of the episode histogram is displayed by default. Figure 92 presents a line-based histogram selected by the settings option.

The x-axis features time intervals, whilst the y-axis features the number of episodes per time interval.

There is a control which acts as series selector, so that multiple annotation information can be showed within single column chart. The series values can represent the number of episodes found in the period or their percentage relative to the sum of all R waves. The chart type can be either bar chart or 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 which toggle the histogram formatting can be found in the monitoring settings section in the settings pane.

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5.10. Events

The events navigator is toggled on a click of the toggle switch between bpm, beats, episodes, events, QT and alerts in the monitoring header section.

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 or instead of the Beats or Episodes navigator. Whereas the beats and episodes sections were using 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 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 time 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;

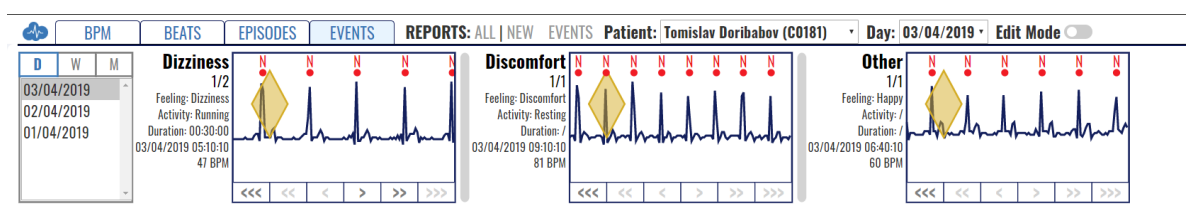


Figure 93: Content section of events navigator.

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 the selected 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 section) has a header on the 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 given time. The presented summary information in the content section corresponds to the period selected by this toggle switch.

The list of dates contains available periods with duration in accordance with 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 info 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, further referred to as 'categories'. The feelings can be set to one of the three predefined: palpitations, dizziness, discomfort, can be custom or can be undefined. The activity can be set to one of the three predefined: resting, active, sports, can be custom or can be 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 category of the event, 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.

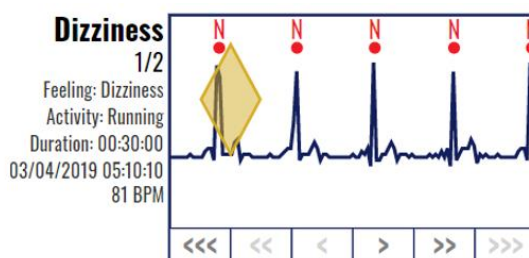


Figure 94: Dashboard of event.

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:

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

Right to the information box there is:

- a display box with an ECG strip presenting the current event, and
- navigation buttons bellow 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 next event in the analyzed period,
 - >> the last event in the analyzed period, and
 - >>> the first event in the next day (if there is such a record).

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

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. A new interface is displayed by clicking the QT TAB (Figure 95).

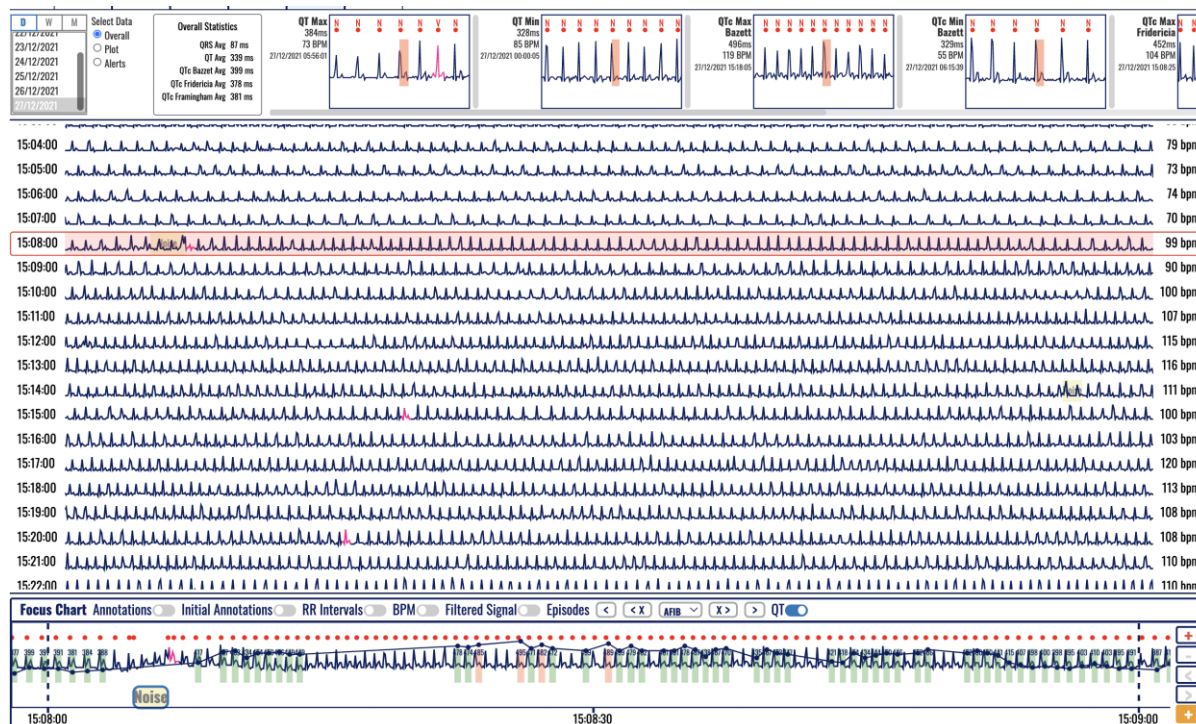


Figure 95: Overall extreme values presented in the QT TAB.

The QT information appears in the area below the deader section (where the of the daily and hour selector are presented for the BPM TAB }.

The region is divided into two sections:

- Control section (Figure 96) – 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 time period;

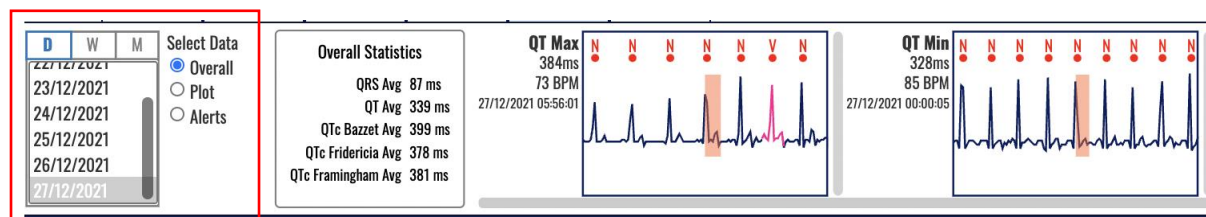


Figure 96: Control section of the QT TAB.

The control section (Figure 96) 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
- Data domain selector with three radio buttons (Figure 97) – located on the right side of the control section and is used to determine whether the content section will contain details (dashboard) about Overall, Plot or Alerts as Selected Data.

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The content section is displayed right from the Control section (Figure 97).

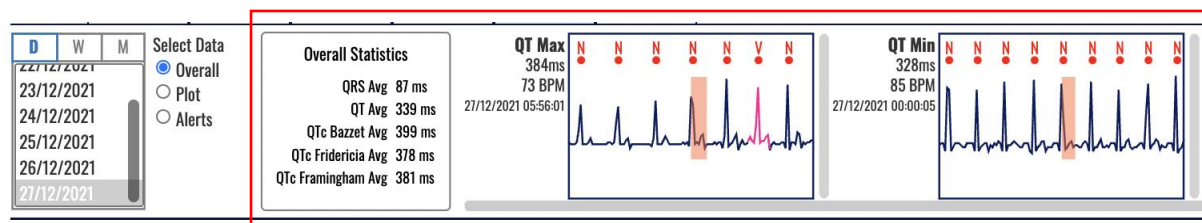


Figure 97: Content section displaying the Overall dashboard of the QT TAB.

Overall dashboard

When Overall is selected from the Select Data radio button group (default option), as presented in Figure 95, the content section is being 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 on 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:

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

Both long and short QT interval values are displayed, as presented in Figure 98. 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 99.

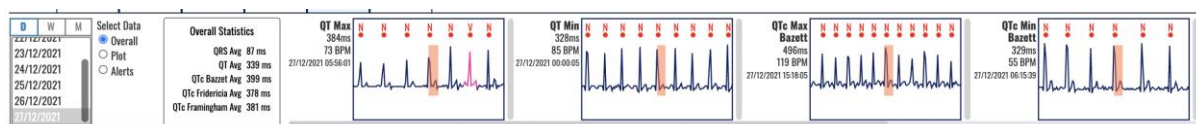


Figure 98: Long and short measured QT intervals and QTc intervals calculated according to Bazett formula.

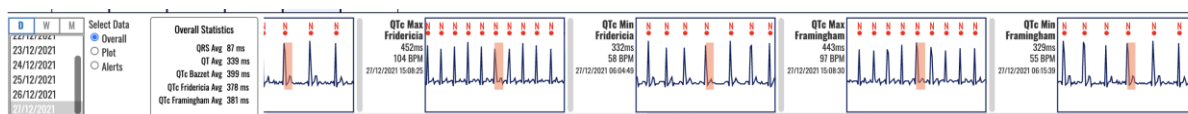


Figure 99: Long and short QTc intervals calculated according to Framingham and Fridericia formulas.

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Clicking on a selected box will open the extended viewer. For example, Figure 100 presents the extended viewer for the selected QTc min according to the Bazett formula.

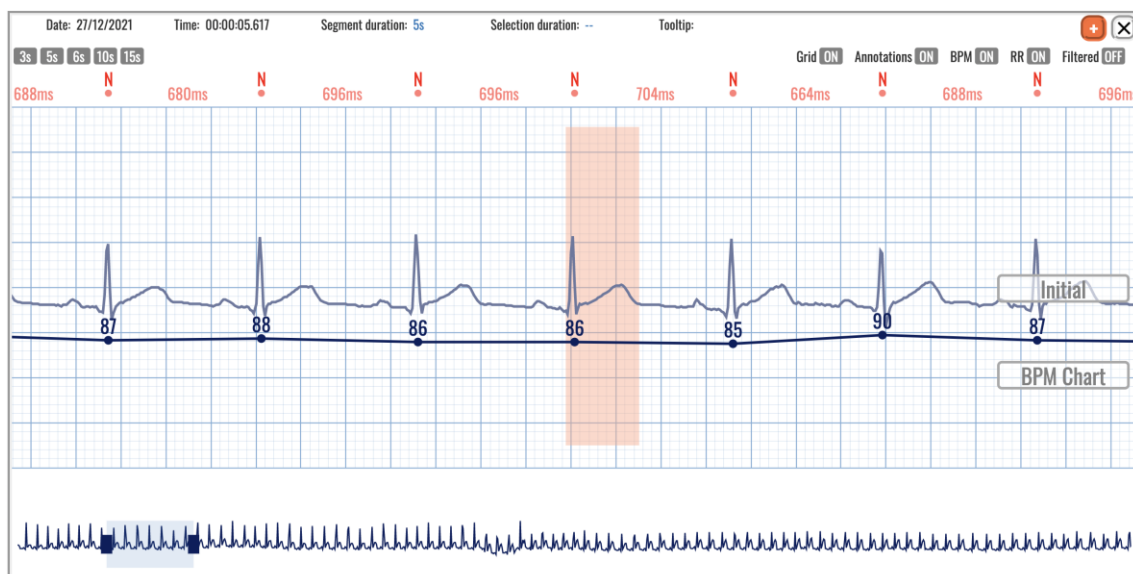


Figure 100: Extended viewer displaying the QTc min according to the Bazett formula.

The extended viewer presents information on the top row, and a set of toggle buttons (Figure 101) to activate the Grid, annotations, information about heart rate (BPM), RR interval in ms and presentation of the filtered signal.



Figure 101: Toggle buttons for better visualization.

An example of presenting the filtered signal is presented in Figure 102.

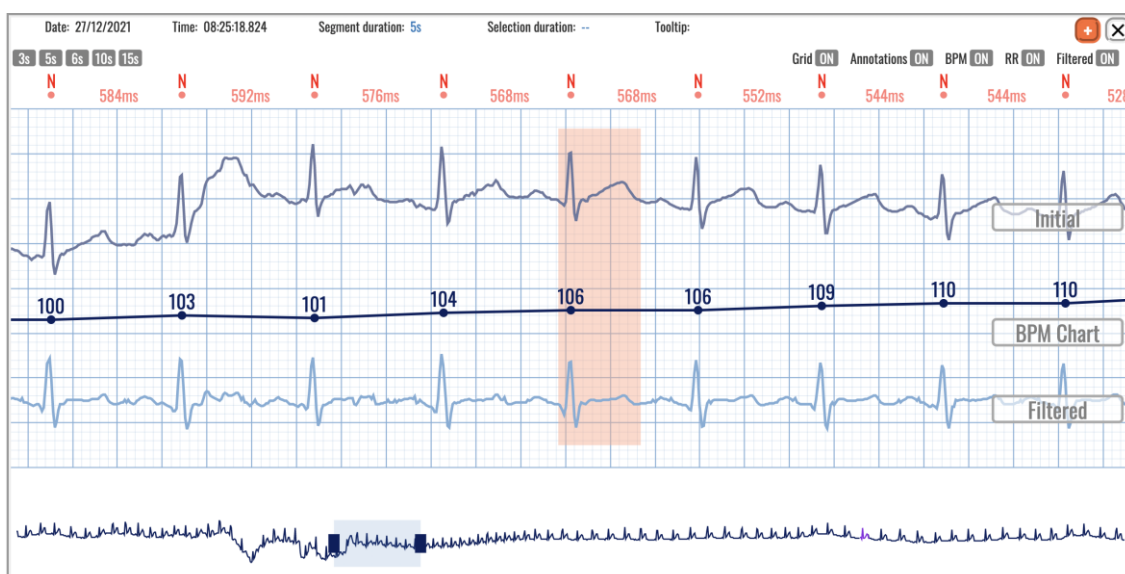


Figure 102: The extended viewer displays the QT interval on the filtered (below) and the ECG (above) signal.

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Clicking on the plus sign with orange background will add the selected ECG strip and marked QT interval in the report. An information box confirms if the adding is successful (Figure 103).

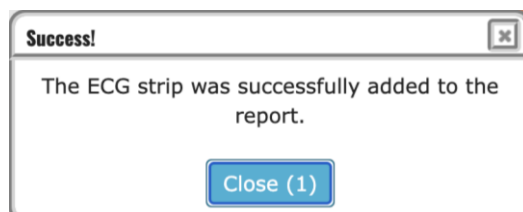


Figure 103: An information window displayed after adding an ECG strip with QT interval in the report.

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Plot's dashboard

Plot dashboard (Figure 104) opens by selecting the Plot option in the radio buttons. In the upper part it 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 by:

- Bazett,
- Fridericia, and
- Framingham.

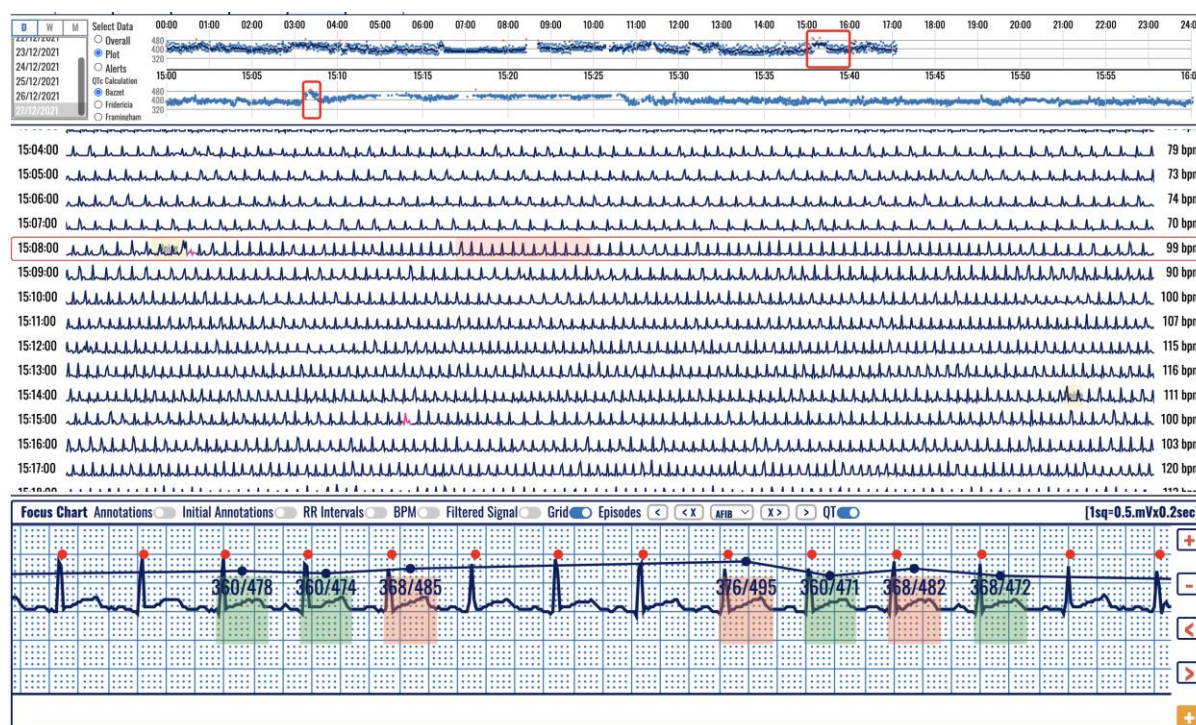


Figure 104: Plot navigation over ECG strips displaying the QT intervals.

The content section (Figure 105) contains presentation of the time series:

- A daily navigator (24-hour plot) that shows one preselected hour which is chosen by default by the availability of data. This plot is clickable and is used to select an hour to be presented in the hourly navigator.
- An hourly navigator (second plot) shows the selected QTc calculation that 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.

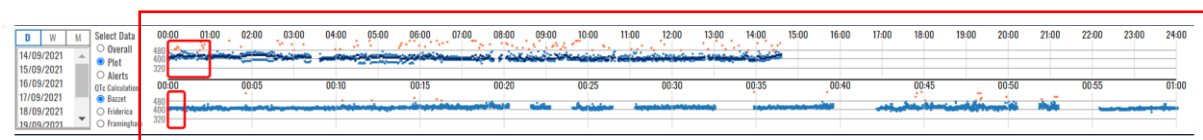


Figure 105: Daily and hourly navigators in the plot dashboard of detected QT intervals.

Both plots contain different colour 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

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

Alerts dashboard

The Alerts dashboard (Figure 106) opens by selecting the Alert option in the radio buttons. It contains the same control section as in the Overall dashboard.

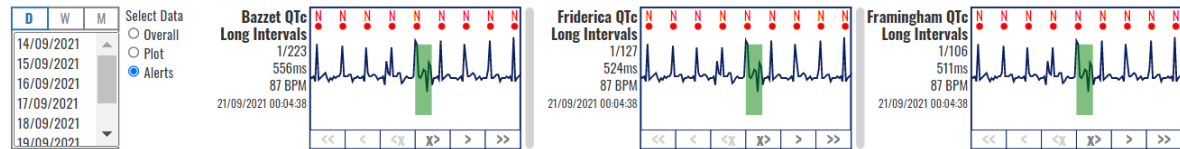


Figure 106: Alerts dashboard.

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 107 presents a long QTc interval calculated according to the Bazett formula, and Figure 110 a short QTc interval calculated according to the Fridericia formula.

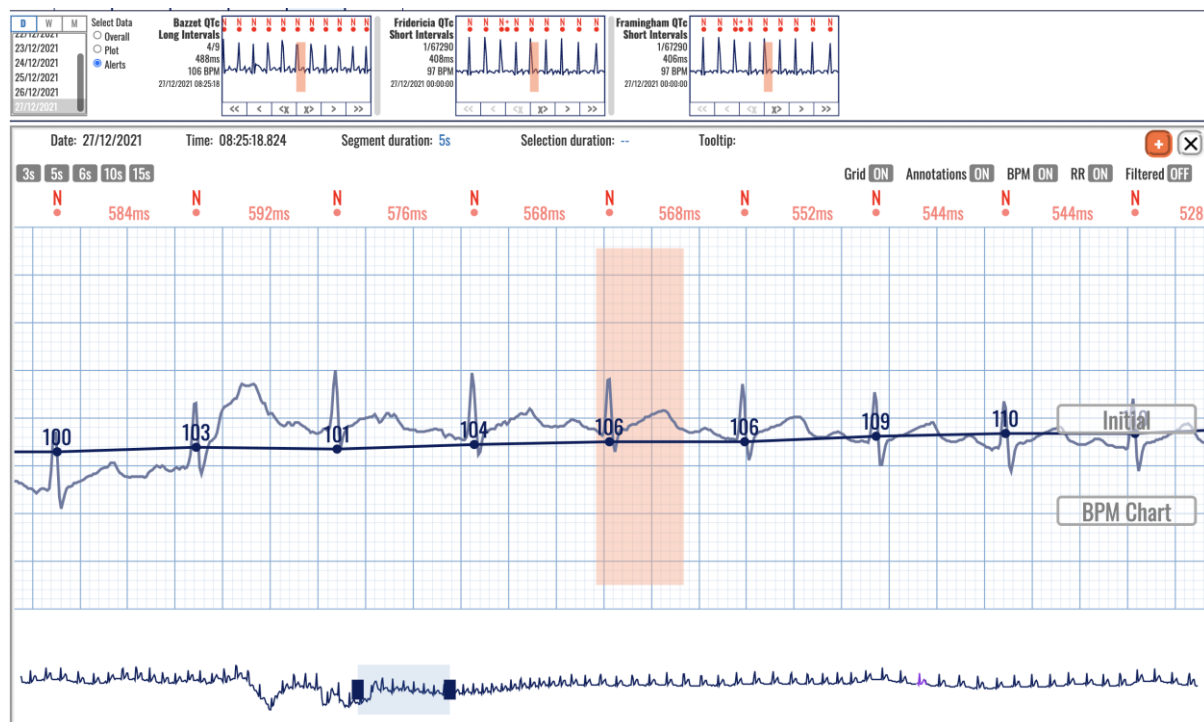


Figure 107: Long QTc interval according to the Bazett formula.

These boxes allow easy navigation through the list of long or short QTc intervals. Six navigation boxes are available (Figure 109), 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 wrong measurement of the QT interval, as presented in Figure 108.

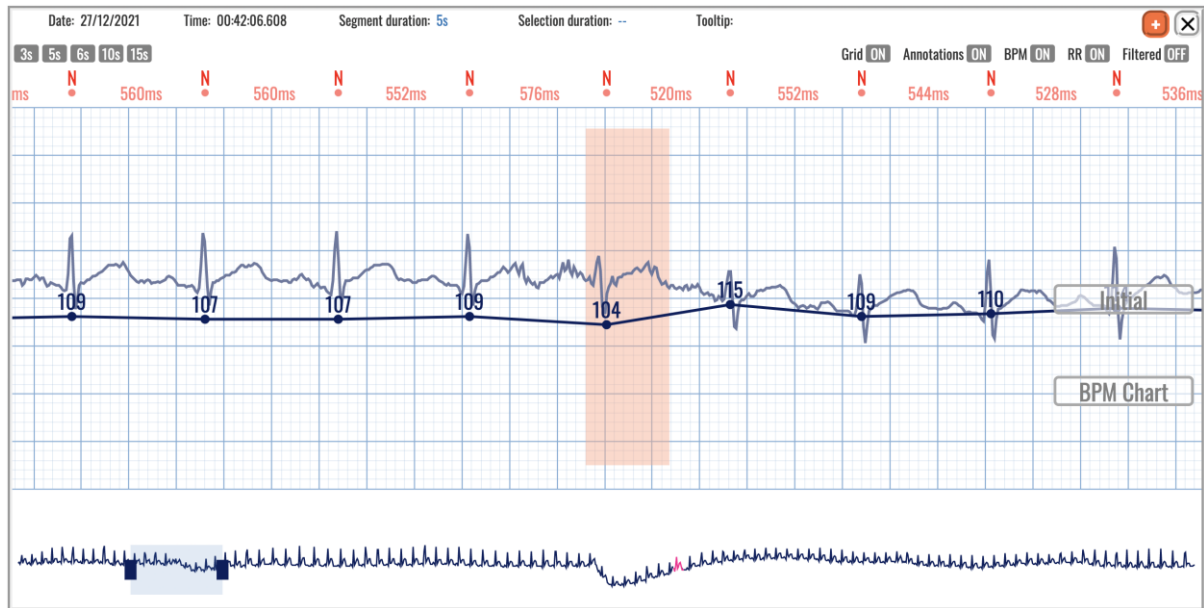


Figure 108: Noise may corrupt proper detection of the QT interval.

Therefore, besides the navigation buttons (Figure 109), 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, while (<X) will delete the current selected QT interval and move to the previous in the list.

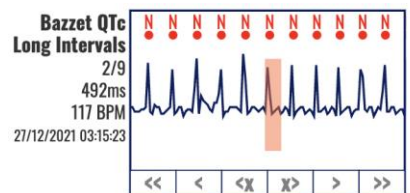


Figure 109: Buttons for deleting and navigation of long QTc intervals according to the Bazett formula.

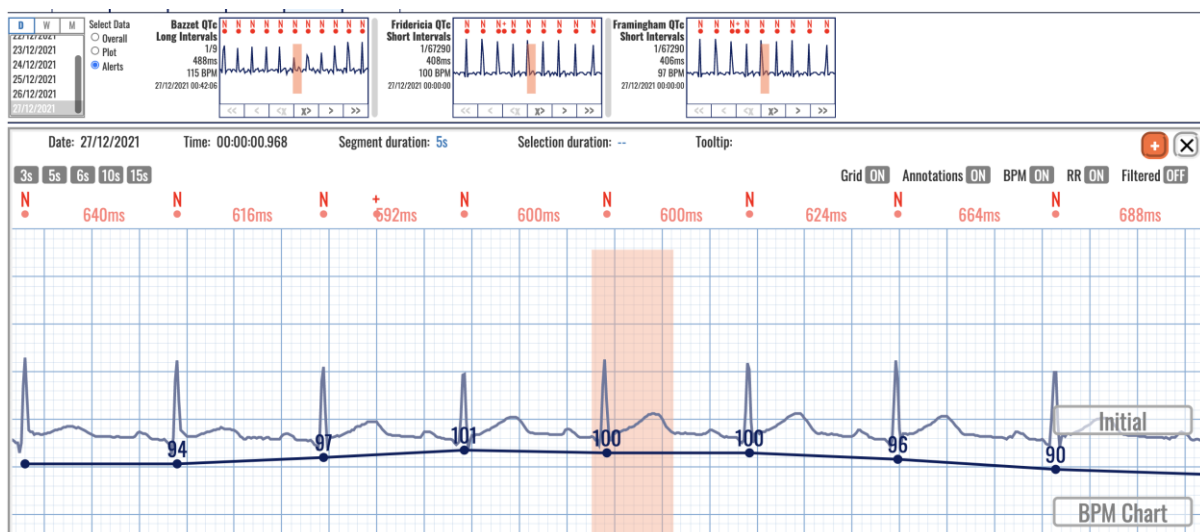


Figure 110: Selected short QTc interval according to the Fridericia formula in the Alarms section.

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5.12. Alerts

The Alerts TAB is one of the options in the list of TABs (BPM, BEATS, EPISODES, EVENTS, QT and ALERTS) in the monitoring header section. A new interface is displayed by clicking the ALERTS TAB (Figure 112Figure 95). The upper part contains the control and content sections (Figure 111).

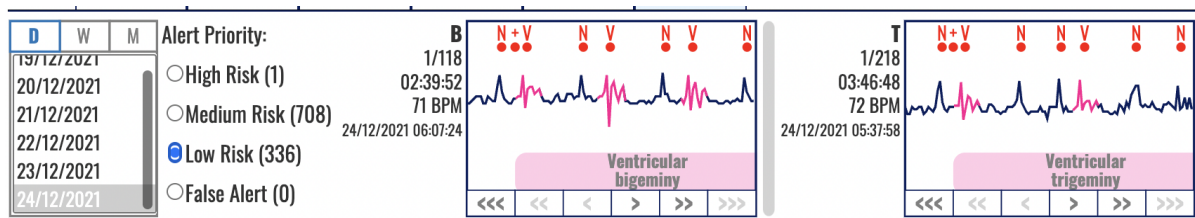


Figure 111: Control and content sections of the Alert TAB.

The control section uses the date selector with three options to select day (D), week (W) or month (M), and navigation list to select a particular day. Right of this date selector is a group of radio buttons to select the risk level for the defined alerts. Figure 111 shows that there is 1 occurrence of high risk, 708 occurrences of medium risk, and 336 occurrences of low risk.

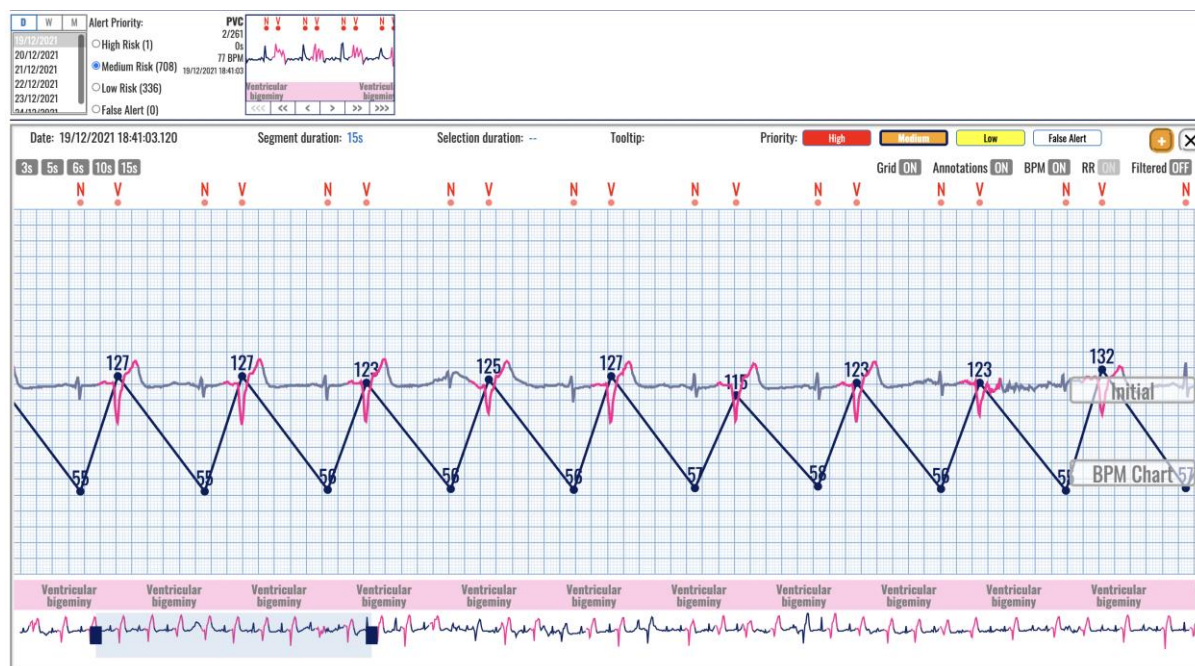


Figure 112: Selected medium risk alerts.

A click in the boxes of detected alerts will open the extended viewer and present details. For example, medium risk alert (as a number of PVC per minute over a threshold) is presented in Figure 112, and low risk (Ventricular trigeminy duration over a threshold) in Figure 113. The thresholds for each patient can be defined as elaborated in Section 4.4 Thresholds.

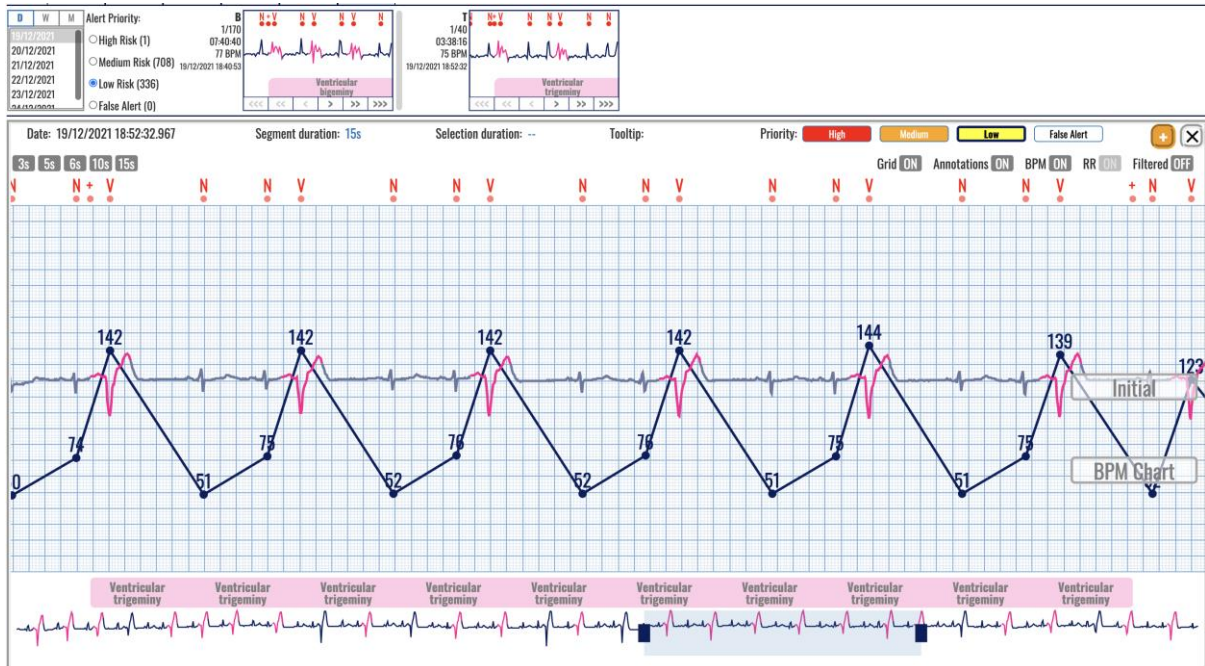


Figure 113: Selected low risk alerts.

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5.13. Extended Viewer

An extended viewer (Figure 114) 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 episodes info is analyzed.

The visualization display box from the content section acts as link to an ECG strip. Upon click, 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, apart from containing the ECG signal visualization window, has a header on its own. The extended viewer header has a timestamp of the annotation which is displayed in the middle, selection duration information (if any), segment duration information, tooltip information, group of buttons to determine the detection type, a button to add to report and a button to close the window of the extended viewer.

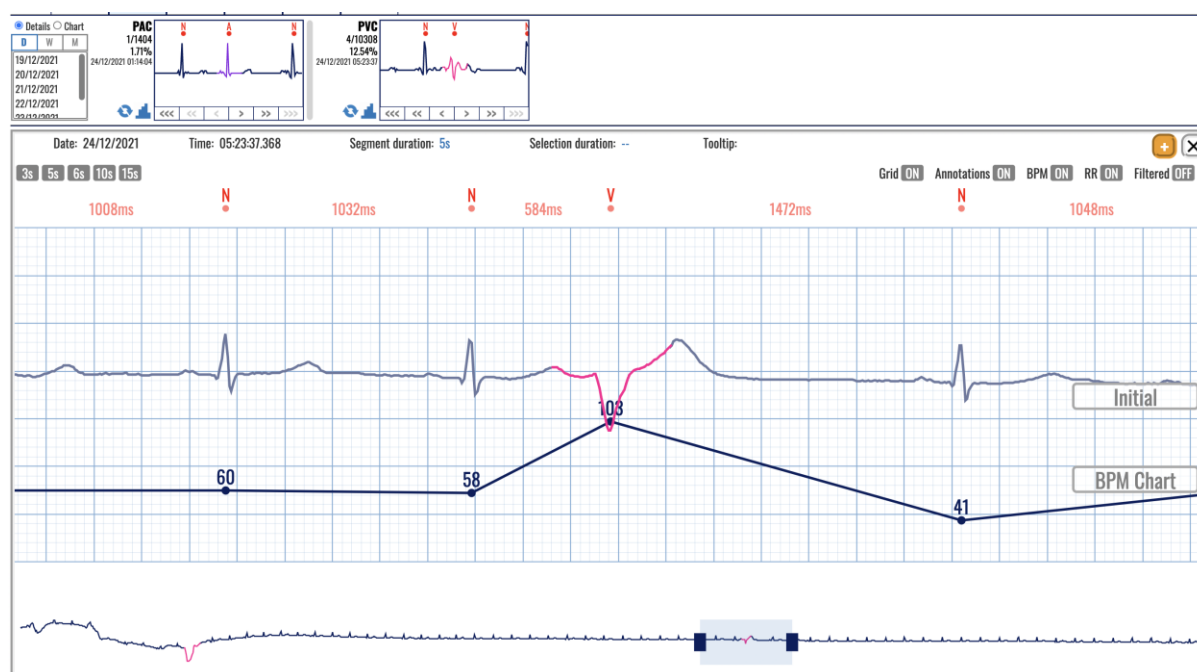


Figure 114: Extended viewer of annotated beats.

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

There is an “add to report” button (Figure 115) which will add ECG strip with duration of 7.5s to the pool of user predefined ECG strips for the report generation. The center point of the 7.5s ECG strip is the center point of the visible part of the ECG strip from the signal visualization pop-up window.



Figure 115: Tools in the header of the extended viewer and the "Add to report" button.

The toggle switches (Figure 115) will display the grid, annotations, heartrate, RR intervals and filtered signal.

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A click on rhythm episode name will open a popup window (Figure 116) to edit the rhythm episode. The episode start and end times are editable and can be changed.

Another episode can be selected by a clicking on an appropriate button that represents another arrhythmia or identification of noise.

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



Figure 116: Popup window to edit a rhythm episode.

The Delete button will delete the selected rhythm episode. A confirmation window (Figure 117) will appear with two options to confirm (Delete button) and cancel the deleting.



Figure 117: 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 that the user can make undo and redo actions to the changes made. The undo action is done by simultaneous press of Ctl + Z button combo, while the redo action is done by simultaneous press of Ctl + Y button combo.

Query string

When the user navigates throughout the ECG recordings in 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 exact same, timewise and magnification-wise. In addition, this feature enables easier sharing of the monitoring page content, by copy-paste action of the full address string of the monitoring page.

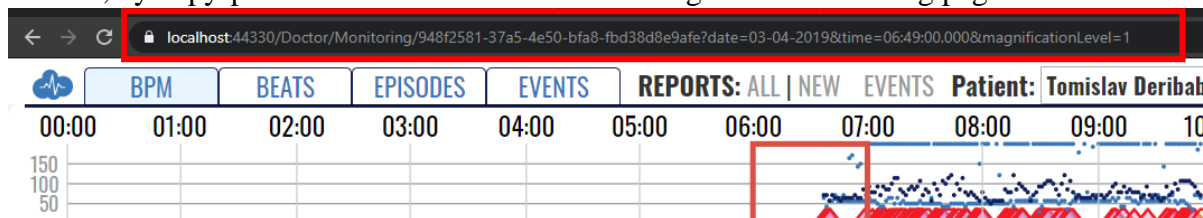


Figure 118: Query string

Beat order number navigation

The user can navigate to a specific beat in the current day data, order-wise. To access this functionality, the user presses the Ctr + F button combination 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 the users with access to the monitoring page.

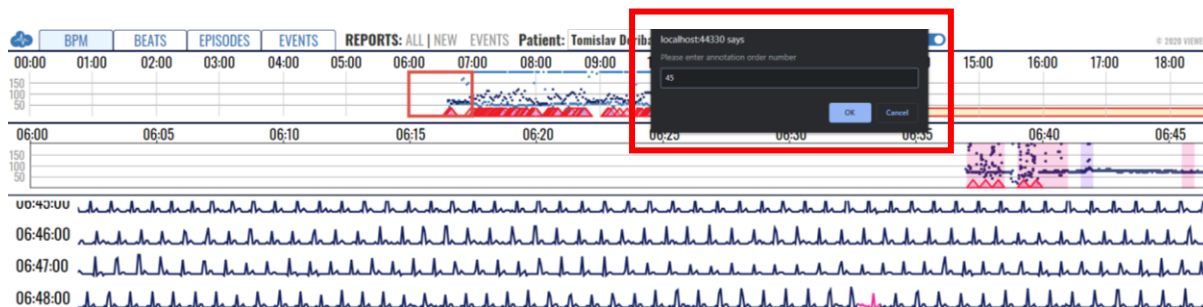


Figure 119: Navigation to specific beat order number

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6. How to create and edit a report

6.1. Create a report

Access the report



Figure 120: Monitoring page header.

A report is created by clicking the “NEW” text link in the monitoring page header (Figure 120). After the report creation page is accessed, the doctor can adjust the measurement period and set a preferred information.

Report Header

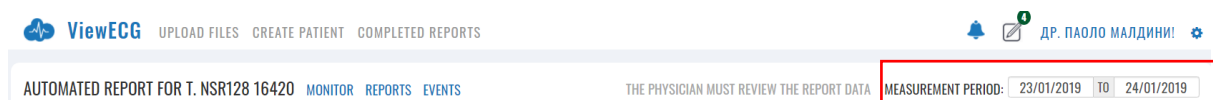


Figure 121: Report header.

The standard application header is located above the custom report header (Figure 121). In the custom report creation page header, the patient full name is placed on the far-left side. Next to the patient name there is quick access section with links to the monitoring, reports and events index pages. On the right there is a measurement period denoted.

Measurement Period

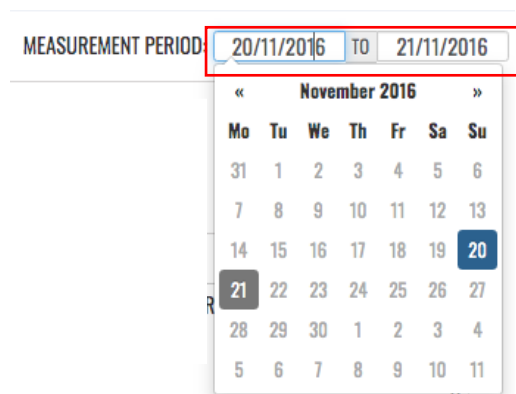


Figure 122: Measurement period selection.

The monitoring period section (Figure 122) consists of two date-picker controls which determine the start and the 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 122 the period is set for the two day long recording session but can be edited to a single day recording if needed.

If there is only one day with measurements for the patient, the report date will be hardcoded on the upper right side of the report header and the user wouldn't be able to change it (Figure 123).

Figure 123: Single day measurement.

In case there are ECG strips added for the report which predate one week before the last recording date, the default period for the report will be set with start date matching the oldest ECG strip and end date which 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 days included in the report period is such that the whole day findings must be included in the report summary information; for example, we cannot exclude the findings before 13:00:00 if we want to include the findings after 13:00:00. A maximum number of 30 days can be included in the report summary information.

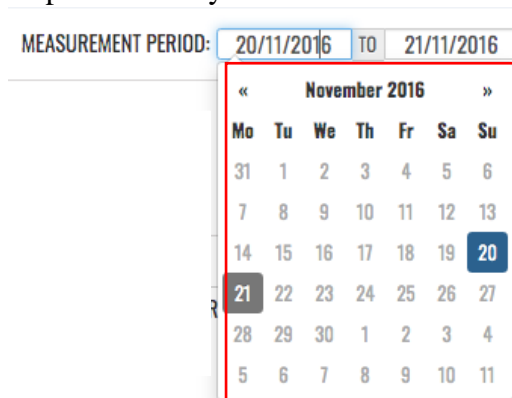


Figure 124: Data selector for the report.

The date picker controls can only select days when measurements were taken. The date-picker controls 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	Age 69
Sex	Male	Height 180 cm
Address	588 Hoffman Avenue	Weight 50 kg
		Pacemaker No
		Medications
		Indications

Figure 125: Patient details section.

The patient details sections (Figure 125) 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 126) 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	/		
VEs per 1000	1	SVEs per 1000	0		
VEs per Hour	6	SVEs per Hour	0		

Figure 126: 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 the report period;
- Normal Sinus Rhythm Duration – the duration of the normal sinus rhythm in the recorded period.
- ECG monitoring period start – the start of the report period; and
- ECG monitoring period end – the end of the report period.

The heart rate section contains information on:

- 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 consecutive hours; and
- Max HR-Hourly – the maximum average BPM value of all consecutive hours.

The pauses and aberrant beats sections contains 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 greater 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:

- 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 longest number of successive ventricular ectopy beets exceeding 5;
- Min HR V-Run - the minimum BPM value of all ventricular ectopy runs exceeding 5 successive beats;
- Max HR V-Run – the maximum BPM value of all ventricular ectopy runs exceeding 5 successive beats;
- VE's per 1000 – average number of ventricular ectopy per 1000 beats; and
- VE's per Hour – 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 longest number of successive supraventricular ectopy beats exceeding 5;
- Min HR SV-Run - the minimum BPM value of all supraventricular ectopy runs exceeding 5 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.

The summary information section, in addition to the mandatory sections, also has a dynamic number of subsections, one for each type of detected episodes 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 longest 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 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 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 with title: 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.

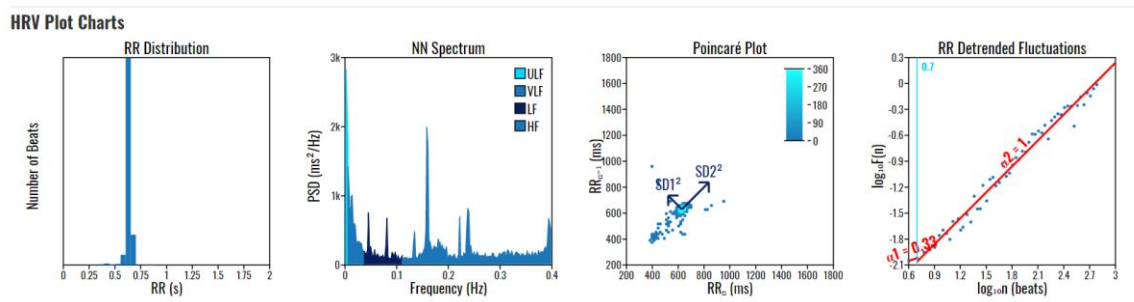


Figure 127: HRV Plot Charts

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6.4. Statistics on Detected Beats and Rhythm Episodes

Detected Beats and their Annotations

The system automatically detects several types of beats, including premature atrial contractions (PAC), premature ventricular contractions (PVC) or fusion beats. They are presented in the dashboard (Figure 128).

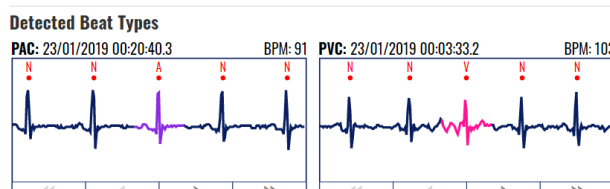


Figure 128: Detected beats and their annotations.

The section provides information box for each annotation detected in the report period. The annotation box contains an abbreviated name of the annotation, an ECG strip of the annotation and navigation buttons bellow 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 as tooltip information on mouse over with the full name of the annotation. A navigation button can be inactive in case such annotation does not exist. In case the content section width is not sufficient to fit all annotation information boxes, the content section is extended in height, meaning that a new line of annotation information boxes will be listed. By clicking the annotation strip, an ECG strip with the next annotation of the same type will be shown in the annotation box, if next such annotation exists. The current annotation will be shown 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 129), including Atrial fibrillation (AFIB), ventricular tachycardia (VT), supraventricular tachycardia (SVTA), Bigeminy (B), and Trigeminy (T).

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

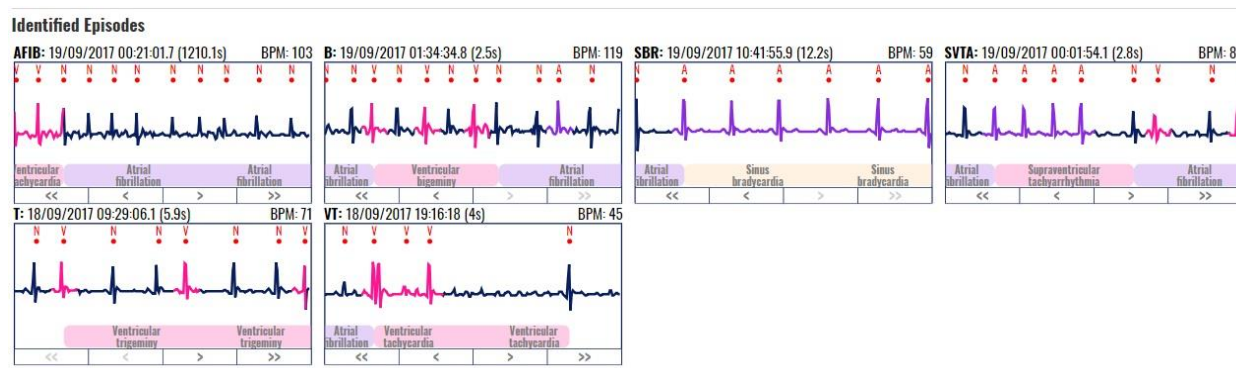


Figure 129: Detected rhythm episodes.

The episode abbreviation and the episode ECG strip have as tooltip information on mouse over with the full name of the episode. A navigation button can be inactive in case such episode does not exist. In case the content section width is not sufficient to fit all episode information boxes, the content section is extended in height, meaning that 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 episode box, if next such episode exists. The current episode will be shown when the report is printed or the report is saved and reopened.

6.5. Histograms and Selected ECG Strips

Significant Histograms

The report contains a section with significant histograms displayed (Figure 130).

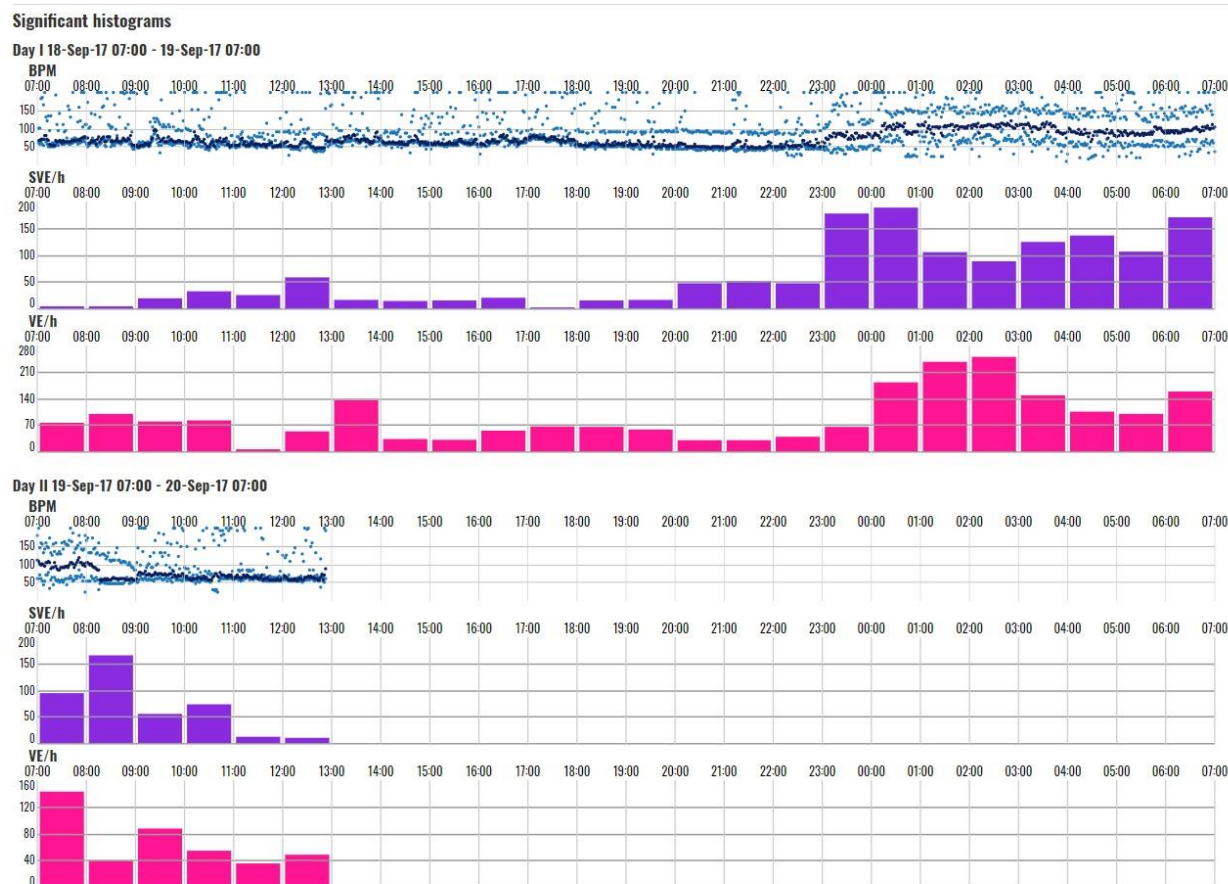


Figure 130: Significant histograms presented in the report.

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 together and an hourly column histogram is drawn;
- VE/h - the ventricular ectopy annotations are grouped together 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.

In case all the values in the column histogram are zero, the column histogram is omitted. On mouse over event on the column histogram columns there is tooltip information on the number of the 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 for 24h.

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Events

Significant events can be shown in the report (Figure 131). 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.

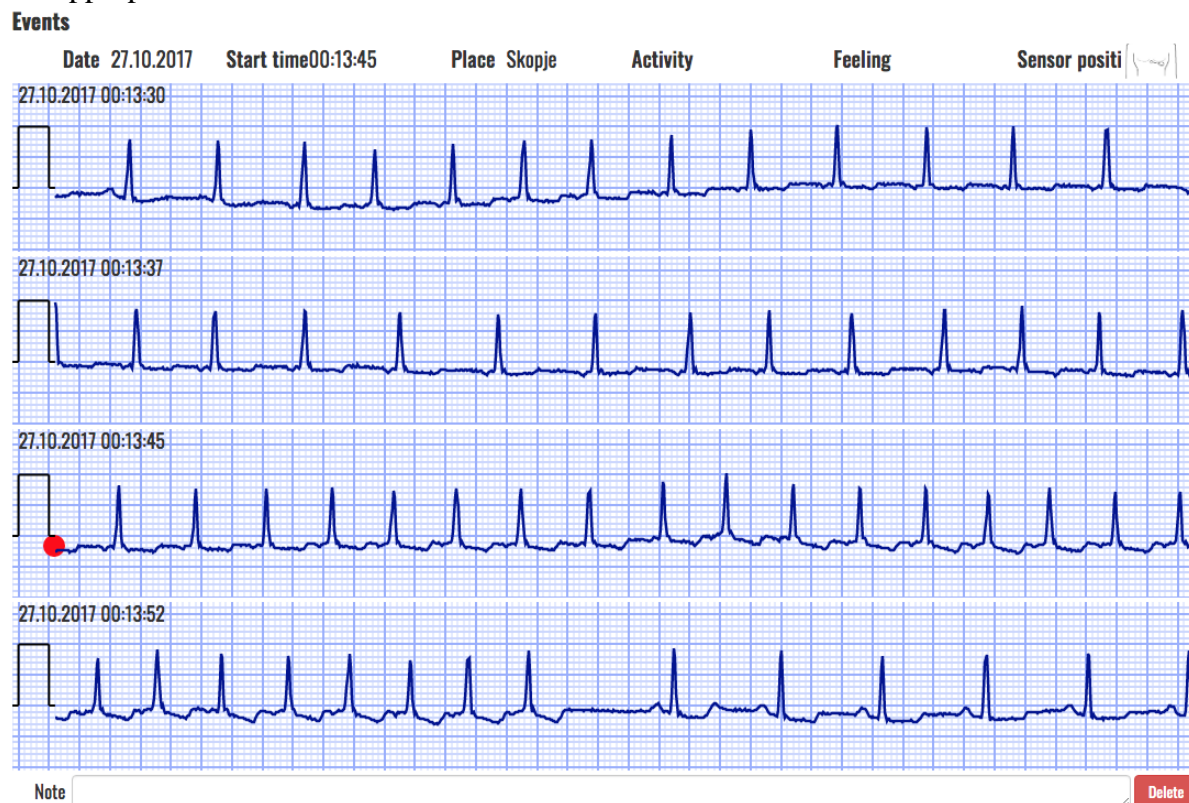


Figure 131: Significant events presented in the report.

Selected segments

The list of selected ECG strip segments by the doctor using the monitoring page is provided in this section. The ECG strips are of duration 7.5s, 15s or 30s. The row is of 7.5s duration, therefore, a strip can span through multiple rows. Each ECG strip is drawn with the standardized ECG grid and it begins with the standard tick symbol.

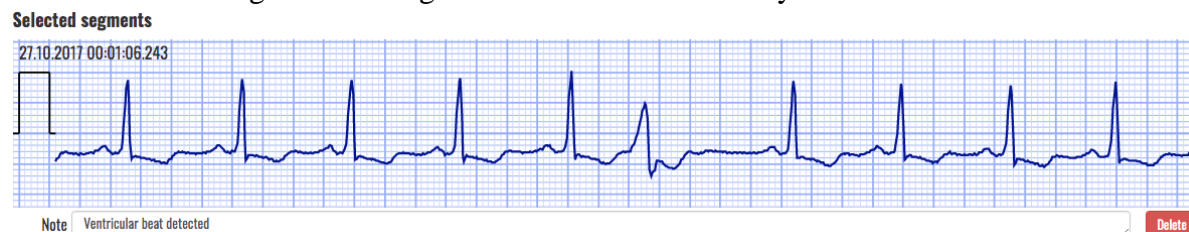


Figure 132: Selected segments presented in the report.

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

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6.6. Report edit

Doctor's report can be accessed to edit certain specifications (Figure 133). Hovering over the desired section of the report, the edit button will appear. A click on the edit button will provide the option to edit parts of the report. Values of the report that can be edited will be shown in a blue rectangle. Simple select and edit action 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 133: Edit button.

General information

The General information section in the report has the option for editing the following value:

- 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 has 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
- SVE's 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 entire section (Figure 134). A confirmation for deletion is required (Figure 135)



Figure 134: Delete button.

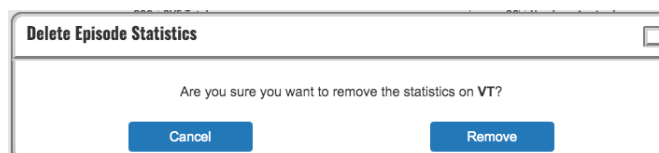


Figure 135: Confirmation for deletion of episode statistics.

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6.7. Writing Opinion and File Management

Opinion

The report opinion has default preset template in the following format (Figure 136):

“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, there were <PAC number> PACs and <PVC number> PVCs 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 136: Form to write an opinion in the report.

The doctor enters his/her opinion for the report in the input text field on the bottom of the report review page.

Action Buttons

File management functions for the report are available via action buttons on the bottom of the report page (Figure 137).

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: Action buttons for file management.

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

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Report Printing

By clicking the “Print” button the user enters the printing dialogue form (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: Print button to activate the printing dialogue.

The report dialogue form (Figure 139) is immediately opened after activating the print functionality and 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).

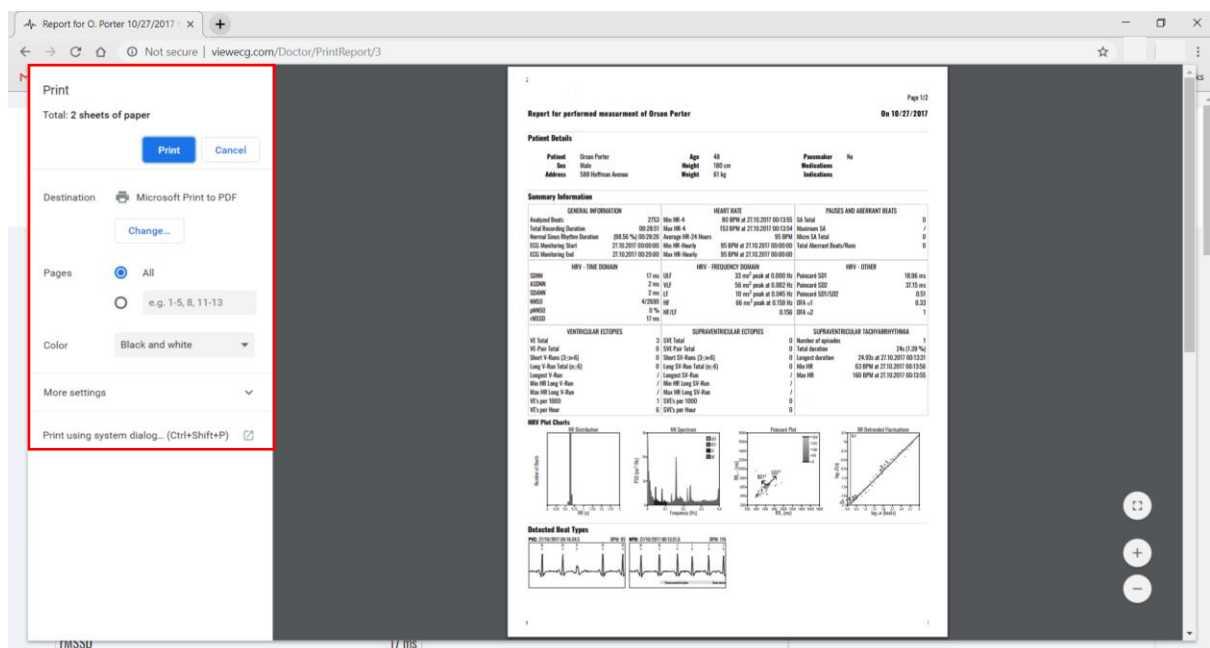


Figure 139: Print dialogue form.

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 printing of the report is optimal for 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 140: 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 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

 INNOVATION

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Figure 141: Printed report sample footer.

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

7. Data Formatting

The Physionet standard for annotations has been supplemented with additional information, such as beat and episode types and color, for the purpose of meeting 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 due to 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 which are part of 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	I	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 that are part of 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 information 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

7.3. Diagnostic options

The essential diagnostic options realized by this medical device are:

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

More detailed list of declared diagnostic options include:

- QRS complex detection
- 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
- QT detection, calculation according to Bazett, Fridericia, Framingham
- ST elevation/depression 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, Poincare plot, and detrended fluctuation analysis.

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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

The doctor in monitoring center should view a list of all current and unresolved health-related events after initial login. They should be clickable (Figure 142).

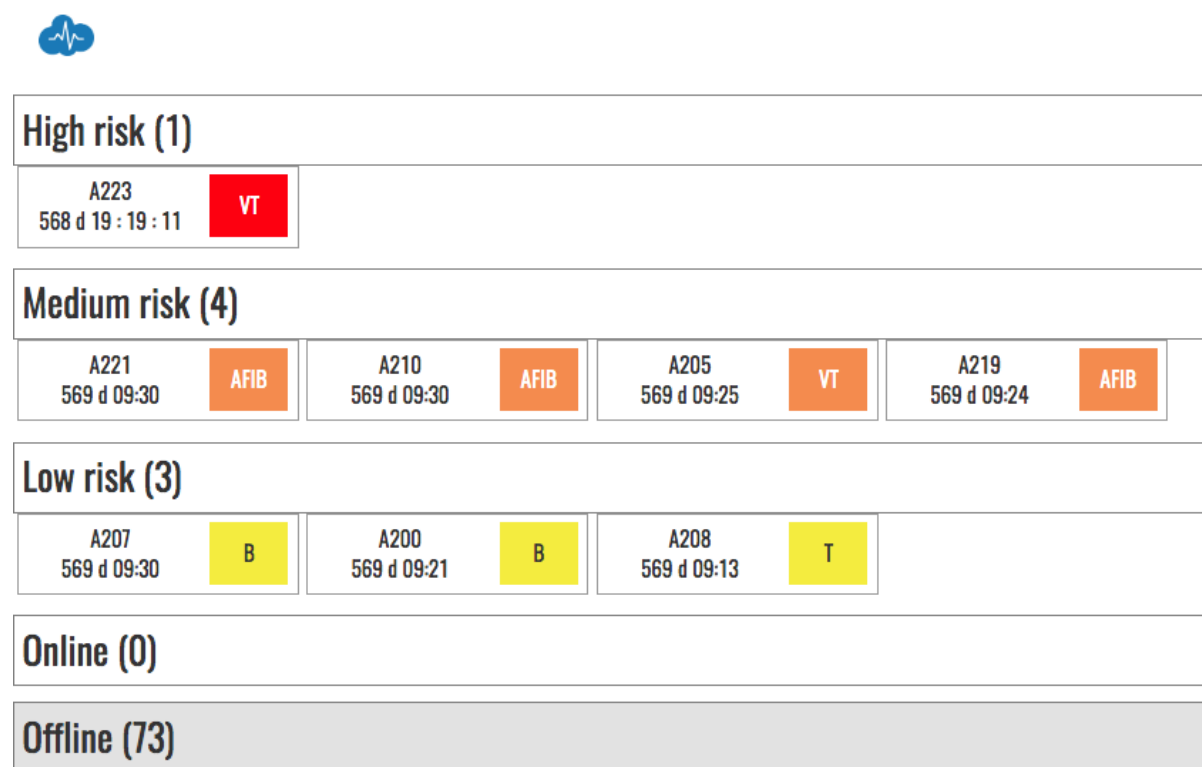


Figure 142: All system health-related events

All resolved events should be stored in an archive. When activated this option presents a list of 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 corresponding monitoring tools are presented in details in the How to use the monitoring tools section.

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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.

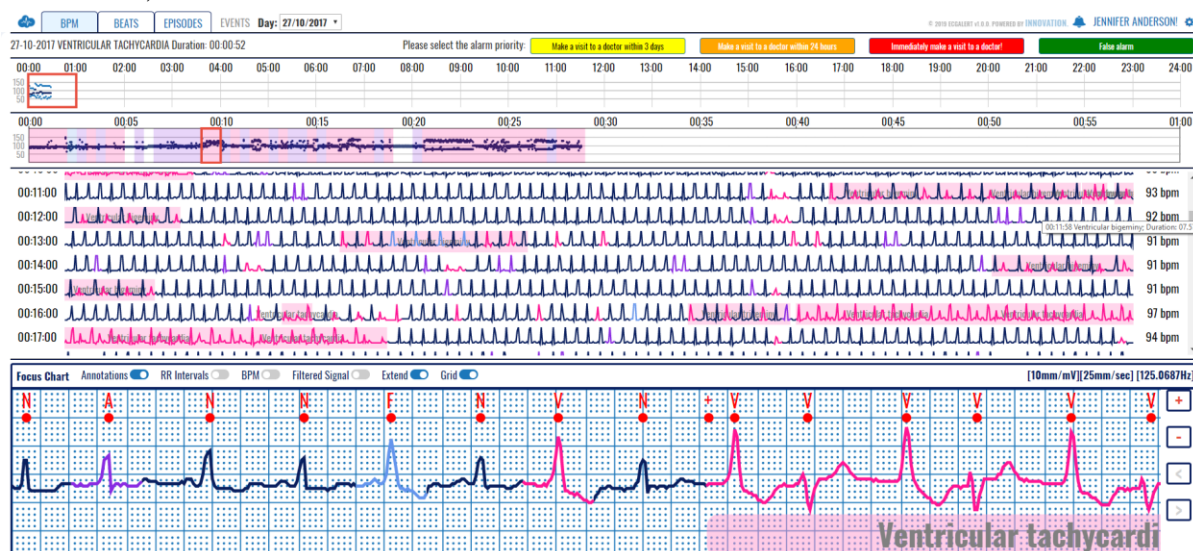


Figure 143: Health-related event monitoring

DOCTOR'S USER MANUAL DUM-009 04.04.2023	APPROVAL:  MARJAN GUSEV General Manager	APPROVAL:  LIDIJA POPOSKA Medical Expert
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