ViewECG

Medical device system Doctor's User Manual

MD

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READ THIS FIRST

First read the safety measures from the Patient's User Manual.



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

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1. Product Description

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 usecase scenarios, as well as information on the format and constitution of the ECG feature findings.

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.

1.1. 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 standard¹ for annotations and episodes.

1.2. Register and login

The doctor needs to be registered by the service provider in order to gain access to the <u>web</u> <u>application</u>. A standard login procedure with username and password is applied to enter the home page.

1.3. Maintenance, compliance, troubleshooting and cautions

These headings are explained further in the patient's user manual.

¹ PhysioBank Annotations - https://www.physionet.org/physiobank/annotations.shtml

2. 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.

2.1. 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	Ν	R		TRUE	FALSE	FALSE	FALSE	FALSE
Premature atrial contraction	PAC	А	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	В	R		TRUE	TRUE	FALSE	FALSE	FALSE
Aberrated atrial premature beat	AAPB	а	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	е	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	Е	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	1	TRUE	FALSE	FALSE	FALSE	FALSE
Sinus Arrest (Pause)	SA Pause	Р	R		TRUE	FALSE	FALSE	FALSE	FALSE
Start of ventricular flutter/fibrillation	VFIB Start	[0	1	FALSE	FALSE	FALSE	FALSE	FALSE
End of ventricular flutter/fibrillation	VFIB End]	0	1	FALSE	FALSE	FALSE	FALSE	FALSE
Ventricular flutter wave	VF Wave	!	R	1	TRUE	TRUE	FALSE	FALSE	FALSE
Peak of T-wave	T Wave	t	Т	/	FALSE	FALSE	FALSE	FALSE	FALSE
Peak of P-wave	P Wave	р	Р	/	FALSE	FALSE	FALSE	FALSE	FALSE
Isolated QRS-like artifact	QRS Artifact	Ι	R	1	FALSE	TRUE	FALSE	FALSE	FALSE
Change in signal quality	Quality Change	С	0	/	FALSE	FALSE	FALSE	FALSE	FALSE
Rhythm change	Rhythm Change	+	0	1	FALSE	FALSE	FALSE	FALSE	FALSE
Comment annotation	Comment	Z	0	/	FALSE	FALSE	FALSE	FALSE	FALSE
Peak of Q-wave	Q Wave	q	Q	1	FALSE	FALSE	FALSE	FALSE	FALSE
Peak of S-wave	S Wave	s	S	/	FALSE	FALSE	FALSE	FALSE	FALSE
ST change	ST Change	ο	S	/	FALSE	FALSE	FALSE	FALSE	FALSE
T-wave change	T Change	х	Т	/	FALSE	FALSE	FALSE	FALSE	FALSE
Systole	Systole	z	0	/	FALSE	FALSE	FALSE	FALSE	FALSE
Diastole	Diastole	d	0	/	FALSE	FALSE	FALSE	FALSE	FALSE
Measurement annotation	Measurement Ann	0	0	1	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	1	FALSE	FALSE	FALSE	FALSE	FALSE
Learning	Learning	I	0	1	FALSE	FALSE	FALSE	FALSE	FALSE
Non-conducted P- wave (blocked APB)	Blocked APB	у	Ρ	1	FALSE	FALSE	FALSE	FALSE	FALSE
Waveform onset	WF Onset	W	0	1	FALSE	FALSE	FALSE	FALSE	FALSE
Waveform end	WF End	w	0	1	FALSE	FALSE	FALSE	FALSE	FALSE
Micro sinus arrest (pause)	Micro SA Pause	М	R	1	TRUE	FALSE	FALSE	FALSE	FALSE
Micro sinus arrest (pause)	Micro SA Pause	b	R	1	TRUE	FALSE	FALSE	FALSE	FALSE
Unidentified	Unidentified	U	R		FALSE	TRUE	FALSE	FALSE	FALSE

2.2. 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	Ν	/	FALSE	FALSE
Atrial bigeminy	AB		TRUE	TRUE
Atrial fibrillation	AFIB		TRUE	TRUE
Atrial flutter	AFL		TRUE	TRUE
Ventricular bigeminy	В		TRUE	TRUE
2° heart block	BII		TRUE	TRUE
Idioventricular rhythm	IVR	/	TRUE	TRUE
Nodal (A-V junctional) rhythm	NOD		TRUE	TRUE
Paced rhythm	Р		TRUE	TRUE
Pre-excitation (WPW)	PREX	/	TRUE	TRUE
Sinus bradycardia	SBR		TRUE	TRUE
Supraventricular tachyarrhythmia	SVTA		TRUE	TRUE
Ventricular trigeminy	Т		TRUE	TRUE
Ventricular flutter	VFL		TRUE	TRUE
Ventricular tachycardia	VT		TRUE	TRUE
Noise	NOISE		FALSE	FALSE
No signal	NOSIGNAL		FALSE	FALSE

2.3. 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
- 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.

3. 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.

3.1. 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).

ViewECG			🌲 🏼 🖉 DEMO DOCTOR
(The second seco	files	Create patient	pleted reports Traft reports
atients 0 ~ entries			Search
	Code	₹ Name	
Monitor Reports Events	A234	Orson Porter	
Monitor Reports Events	A233	Carter Ferguson	
Monitor Reports Events	A232	Gordon Reginald	
Monitor Reports Events	A231	Samuel Orson	
Monitor Reports Events	A230	Peter Wolf	
	A228	Ronald Washington	
Monitor Reports Events			
Monitor Reports Events Monitor Reports Events	A223	Theodore Mercury	
	A223 A222	Theodore Mercury Wallace Lennon	
Monitor Reports Events			

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.

			_						
<<	<	1	2	3	4	5	6	>	>>

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.

	۶	ß	DEMO DOCTOR!	٥	
Notifications					×
No new notifications in	1 this se	ssion!			

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.

Notifications	×
Upload files	
test.s2: Processing finished successfuly.	

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.

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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.

w 10		Search:	
•	Created on $\downarrow \vec{r}$	Patient 11	
	31.08.2018 17:54:09	Wallace Lennon	Û
	30.08.2018 12:18:02	Burt Reynolds	Ŵ
	30.08.2018 12:15:28	Reginald Mars	Û
	21.08.2018 15:41:16	Orson Porter	Û
	20.08.2018 14:53:52	Reginald Alorso	Ŵ

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 rep	orts selected.	
Are you sure that	you want to delete sel	ected
reports?		

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.

٤	Þ	DEMO DOCTOR!	٥
		PROFILE	
		LOG)FF

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.

Title		User name (Email)	demodoctor@ecgalert.com
name	Demo	Password	Change your password
me	Doctor	Code	D1000
x	● Male ◎ Female	Language	English (United States)
th	6/25/1980	Picture	Remove file
SS	Ocean View 1251		Save
ity	Los Angeles		
le	90066		
ry	United States 🔻		
er	0215454545		

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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3.2. Most used functions

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

Upload files	Create patient	Completed reports	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 t	he amount and size of the	files. Please be patient.
Patient	Choose	~
Files	Browse	
	You can upload more than one file	9.
	Start transferring	

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.

			∎ s2 ≎		Q Search
		Name	Date Modified V	Size	Kind
		2017-07-11_183430.s2	11 Jul 2017, 6:34 PM	8 KB	Document
		2017-07-11_182530.s2	11 Jul 2017, 6:26 PM	15 KB	Document
		test.s2	11 Jul 2017, 6:26 PM	15 KB	Document
Upload files		2017-07-11_110500.s2.nekge	11 Jul 2017, 11:24 AM	11 KB	Document
		c correct.c	11 Jul 2017, 11:22 AM	2 KB	C Source
Uploading files time deper	id of the a	bb1.s2	11 Jul 2017, 11:21 AM	12 KB	Document
		Cr Cr	11 Jul 2017, 11:21 AM	9 KB	Unix ecutab
		2017-07-11_110730.ecg	11 Jul 2017, 11:09 AM	44 KB	Document
		2017-07-11_110800.ecg	11 Jul 2017, 11:09 AM	15 KB	Document
Patient	Alex Jobs	2017-07-11_110730.s2	11 Jul 2017, 11:08 AM	27 KB	Document
		2017-07-11_110500.s2	11 Jul 2017, 11:08 AM	21 KB	Document
Files	Browse	2017-07-11_110530.ecg	11 Jul 2017, 11:08 AM	15 KB	Document
Thes	DIOWSC	bb.s2	11 Jul 2017, 11:00 AM	12 KB	Document
	Vau aan un	2017-07-11_104430.s2	11 Jul 2017, 11:00 AM	12 KB	Document
	You can up	headerLAST.s2	11 Jul 2017, 10:37 AM	1 KB	Document
		header1.s2	11 Jul 2017, 10:23 AM	1 KB	Document
		bt1.s2	11 Jul 2017, 7:31 AM	1 KB	Document
	Upload	Ch. eOle	44 LUI 0047 7-04 AM	0.80	Taut?d
		Options		Can	el Open

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			Email		
Last name			Password		
Date of birth	6/25/1979		Confirm password		
Sex	• Male • Female		Pacemaker 🗆		
Weight	70		Indications		ĥ
Height			Medications		
Arrived on	6/25/2019	iii	Company	Test Cardiology	\$
Device	Choose	\$			
Crea	te				

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

Patient 11	Period 11	Opinion Ut	Created on
Ronald Washington (A228)	27.10.2017	Underlying rhythm is normal with rates between 54 and 80 BPM. Frequent (20) episodes of ventricular bigeniny 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
Drson 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
ohn 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 entri 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.

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3.3. 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.

late	REPORTS MONITOR			
ow 10 🔹	entries	Sea	arch:	
Date ↓₹	Time	.↓₹ Ac	tivity 💵	Feeling 11
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			

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 dropdown 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.

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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.

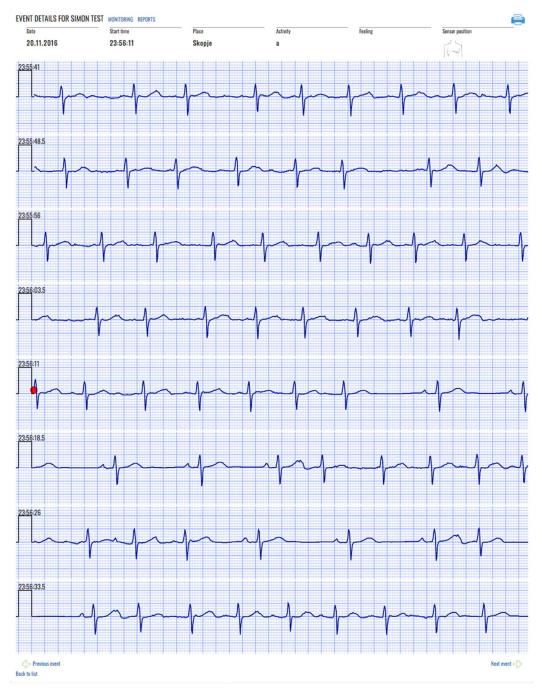


Figure 18: A sample of recorded event.

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.

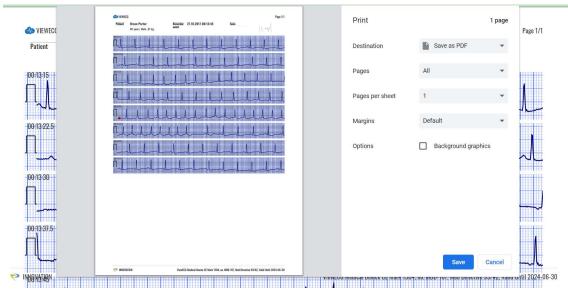


Figure 19: Dialog form to print an event.

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.

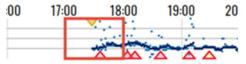


Figure 20: Events in BPM, Beats or Episodes navigator.

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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.

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173000	-
123100 +++++++++++++++++++++++++++++++++++	1
12200 J.	1
12300	ŧ.
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17360 ••••••••••••••••••••••••••••••••••••	6
12300 + + + + + + + + + + + + + + + + + +	e.
8189 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	£.
9199 AAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA	1

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.

Focus Chart	Annotations 🌑 🛛 RR Intervals 🗇	BPM COD Eithared Signal COD	Extend 🜑		
			11111		
					 hhhhhhhhhhh
:			and and		
				V	
17/2/00				172730	17.28.00

Figure 22: Event in Focus chart.





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Figure 23: A pdf corresponding for recorded event.

4. 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.

4.1. Main monitoring page

Page overview

When the monitoring tools are invoked, the system displays the main monitoring page (Figure 24).

BPM		EPISODE	SEVEN			REPORTS	ALL LAPS	TUTUTO .			opy (DCP_001		uest.e	cgalerico	Day: 21		T 174 14					DR. PAOL	
D:00 01:00	BEATS 02:00			05:00	06:00	07:00		09:00	10:00	11:00	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00	24:0
		AM /100					-																
):00	00;05		00;10		00;15		00;20		00;25	_	00;30		00;35		00;40		00;45		00;50	_	00;55		01:0
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			~~~~	_		~~~~~			<u> </u>	_						<u> </u>			_	_	<u> </u>		
):00:00			·····	-	4		+~	+-+-					~ * * *		m		<u></u>			····		<b>4</b> 84	bpm
):01:00	····	<u> </u>	····	····	<u> </u>		~~	· · · ·		····				<u> </u>	····	un	····		~~~~	····	· · · ·	87	bpm
:02:00	ma		····	u	····		<u> </u>			in	A Situs kr	adycardia	m			un		<u> </u>		uu		84	bpm
:03:00 mm	whind	mar	und	min	white	man	un	di de marte	-	much	and	hunder	rain	in	Inde	Lun	march		nala	under	alan	and 83	bpm
04:00						Since beerly	ania A		A A Since	heedwardia		A A silve	A A A Sin	us herdward	a A Sinus h	odwardia Sir	us headward	12 A A A				82	hnm
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cus Chart Ar	nnotations 🔍	RR Interv	als 🗩 🛚 B	PM 💽	Filtered :	Signal 🔘	Extend	D															
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1																							
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84 84 84 84 83	••••																					1	

#### Figure 24: 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 25) is made up of four main sections:

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

6	BPM	BEATS	EPISO	REF	PORTS:	ULL   NEW	EVEN	IS Pat	ient: De	mo Patie	ent P (AO	02)	Mo	oni	to	rin	gI	hea	ad	er											Ø DR.	PAOLO M.I
150 100 50 17:00	01:00	17:05	03:00	<b>04:00</b> 17:10	00		17:15	01:01	BPI	ו••	Bea		, E	pis		des		or E		ent	าลง		ate	or	JU R	17:4	13:00	50	21:00	17:55	23.0	U 243
	0 0		LAAA			 											ЛЛ. ЛЛ.							Λ.Λ.  .  .	<u></u>							87 bpm 89 bpm 77 bpm
17:31:00 17:32:00 17:33:00																																73 bpm 73 bpm 73 bpm 74 bpm
17:34:00 17:35:00 17:36:00														st.	of 	EC	G	lst UU				11										73 bpm 75 bpm 77 bpm
Focus C	hart Anno	otations 💽	RR Inte		BPMC	Filt	ered Sigr		Extend			,,,,			oc	us	cl	har			سالم							ll				

#### Figure 25: 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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### 4.2. 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 26), the user is redirected to the doctor's home page.

1.00									
4	BPM	BEATS	EPISODES	EVENTS	QT	ALERTS	REPORTS: ALL   NEW EVENTS Patient: Orson Porter (DCP_00264)	✓ Day: 15/02/2021 ✓ Edit Mode ○ 0	🌲 🖉 DR. ROBERT WILLIAMS! 🌣

#### Figure 26: ViewECG icon is acting as home page link.

### **Choose a patient**

By clicking the "Patient's name" (Figure 27), 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.

🐟 BPM BEATS EPISODES EVENTS OT ALERTS REPORTS: ALL INEW EVENTS Patient: Drsm Parter (DCP_00264) 🗸 Day: (15/02/2021 🗸 Edit Mode DR. ROBERT WILLIAMS) 🧔

Figure 27: Choose a patient for monitoring.

### Choose a date

By clicking on the "Date" (Figure 28), 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.

ep.	BPM	BEATS	EPISODES	EVENTS	QT	ALERTS	REPORTS: ALL   NEW EVENTS Patient: Orson Porter (DCP_00264)	15/02/2021 ~	Edit Mode 🤇	DR. ROBERT WILLIAMS! 🌣

Figure 28: Choose a date for monitoring.

### Edit mode

By clicking on the "Edit mode" switch (Figure 29), you can toggle between the option to edit the automatic diagnosis provided by the software or manually add new episodes of arrhythmias.

😓 BPM BEATS EPISODES EVENTS QT ALERTS REPORTS: ALL I NEW EVENTS Patient: Orsen Porter (DDP_00284) 🗸 Day: [15:02/2021 🗸 Edit Mode 🗆 👁 🌲 🖉 Dr. ROBERT WILLIAMS: 👁

Figure 29: Edit mode toggle switch

### **System notifications**

The "Alarm icon" (Figure 4) used for system notifications is explained earlier.

### 4.3. 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 30) 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.

👍 BPM BEATS EPISODES EVENTS OT ALERTS REPORTS: ALL (NEW EVENTS Patient: Orsan Porter (DCP_00264) 🗸 Day: 15/02/2021 🗸 Edit Mode 🚥 o 🌲 🖉 Dr. ROBERT WILLIAMS o

Figure 30: Link to completed reports (electronic health record) for the selected patient.

### **Events**

The "Events" link (Figure 31) leads to a list of the events, the patient has specified while wearing the wireless sensor.

```
🧆 BPM BEATS EPISODES EVENTS QT ALERTS REPORTS: ALL INTY EVENTS Patient: Orsen Porter (DCP_00264) 🗸 Day: [15/02/2021 🗸 Edit Mode 🗆 O 🔺 🖉 DR. ROBERT WILLIAMS! 🔿
```

Figure 31: Link to events for the selected patient.

### All draft reports

The "Draft reports" icon, located next to the alarm icon (Figure 32) 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.

	0	BPM	BEATS	EPISODES	EVENTS	QT	ALERTS	REPORTS: ALL   NEW EVENTS Patient: Orson Porter (DCP_00264) Day: 15/02/2021 V Edit Mode 💷 O		🖉 DR. ROBERT WILLIAMS! 🔅
--	---	-----	-------	----------	--------	----	--------	---------------------------------------------------------------------------------------------	--	--------------------------

Figure 32: One draft report notification.

### Username and settings

The username and settings icon found at the top most right corner (Figure 33) are used to log OFF, change user profile information, or setup the settings for monitoring tools.

🚷 📴 BEATS EPISODES EVENTS QT ALERTS REPORTS: ALL J NEW EVENTS Patient: Groen Porter (DCP_00264) 🗸 🛛 🖉 Day: (15/02/2021 🗸 Edit Mode 🖜 🖉 🗗 DR. ROBERT WILLIAMS: D

Figure 33: Settings option.

### Monitoring Settings

The monitoring settings menu (Figure 34) 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.

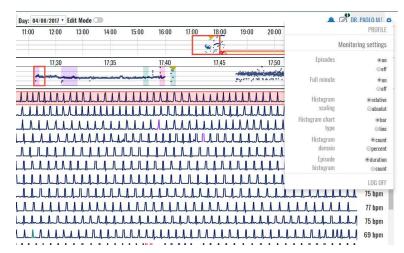


Figure 34: Settings page of the monitoring page.

### 4.4. 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 35) 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 35: 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 36) 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.

00:00 00:	00:10	00,15	00.20	00:25	00.30	00:35	00:40	00:45	00,50	00:55	01;00
	Section and the section of the secti	and and interior	adiration statem	-	in the second		Contraction of the second	in the second	THE PARTY NAME		and the second

#### Figure 36: 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.

### 4.5. 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 37, Figure 38) 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 bandpass 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.

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#### Figure 37: List of ECG strips.

One ECG strip is indicated by a red bordered rectangle around the line (Figure 38). 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 38) can be dragged towards left or right so that the focus chart horizontal offset is adjusted.

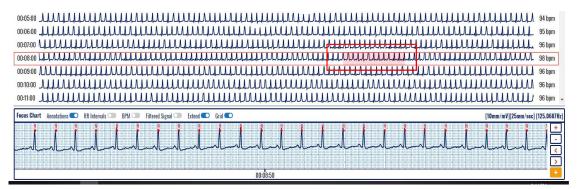
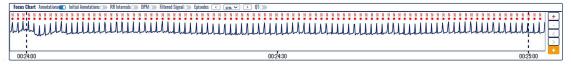


Figure 38: An ECG strip with selected segment to be displayed in the focus chart.

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### 4.6. Focus chart

The selected ECG strip from the displayed list is presented in greater details in the Focus chart (Figure 39). 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 40).



#### Figure 39: 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 40). 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 40). 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 40: A focus chart with identified beats and rhythm episode.

### **Magnification levels**

There are four different levels of magnification:

- X1 the focus chart visualization window fits to the entire ECG strip (Figure 41);
- X2 the focus chart visualization window fits to half the length of the ECG strip (Figure 42);
- X4 the focus chart visualization window fits to fourth of the length of the entire ECG strip (Figure 43); 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 44).

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.

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Figure 41: Selected ECG strip segment and focus chart presenting annotated beats.

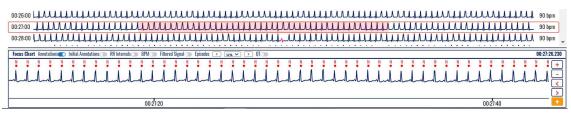


Figure 42: Selected ECG strip segment with 2x magnification and focus chart presenting annotated beats.

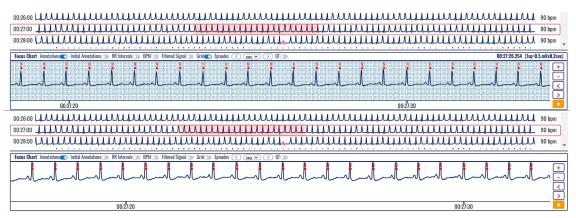


Figure 43: Selected ECG strip segment with 4x magnification and focus chart presenting annotated beats.

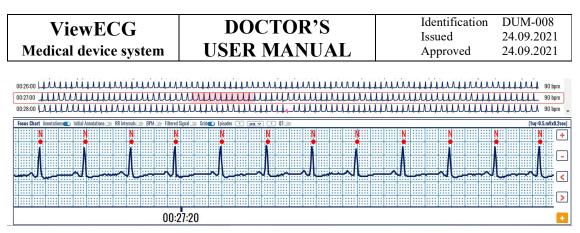


Figure 44: Selected ECG strip segment with 8x magnification and focus chart presenting annotated beats.

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.

### 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 Bazzet, Friderica and Framingham; and
- Episodes drop down menu selects between the available episodes and navigates between the previous and next one.

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#### 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 45, Figure 46, Figure 50 and Figure 51). When annotations are not displayed, then each detected heartbeat is marked only by a red dot (Figure 47, Figure 48 and Figure 49).

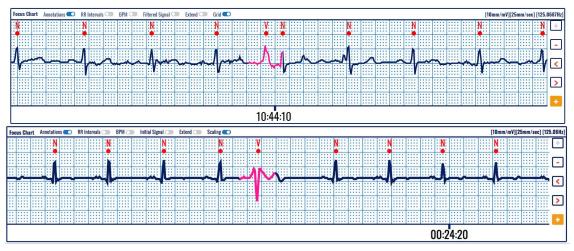


Figure 45: Focus chart presenting annotated beats of an ECG strip on a predefined grid.

Grid is usually used in ECG strips (Figure 45) 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 46) is scaled to the allowed height.



Figure 46: Focus chart of annotated ECG strip presented without grid.

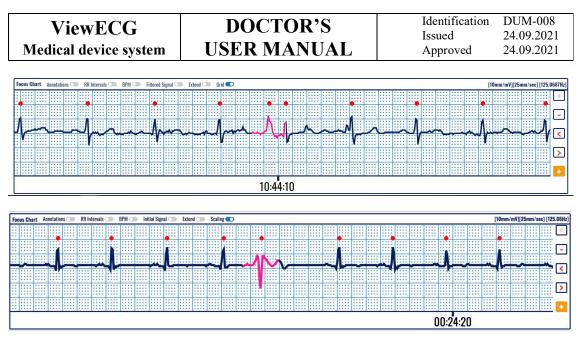


Figure 47: Focus chart presenting an ECG strip on a predefined grid.

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## Extended heart rate-related info

When corresponding toggle switch is activated, then the RR intervals are displayed in seconds (Figure 48) to represent distances between detected consecutive heartbeats.



Figure 48: 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 49).

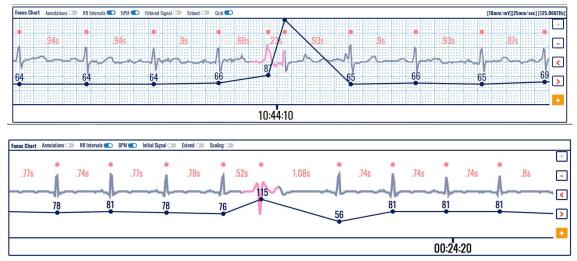


Figure 49: Heart rate information along with RR intervals on the focus chart.

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#### **Extended visualization features**

The filtered ECG recording (Figure 50) 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.

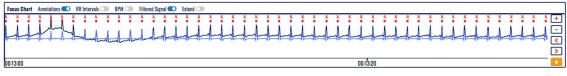


Figure 50: Filtered ECG recording presented on top of the annotated original signal with RR intervals.

Sometimes, a beat may occur in the very begging or ending of the ECG strip, and therefore, it is very difficult to analyze it in a broader context. The extend feature (Figure 51) 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.

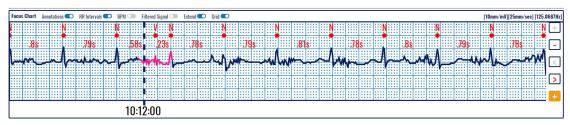


Figure 51: Extend segment function used on focus chart on a predefined grid.

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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.

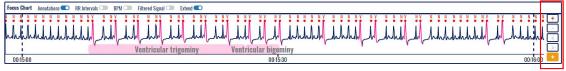


Figure 52: An extended display of the ECG in the focus chart (1 sec out of 30 sec borders).

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 mash is drawn behind the ECG signal and "[10mm/mV][25mm/sec] [125.06Hz]" 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.

## QT

Once the QT button from the Focus Chart is activated, the Focus chart provides QTc drawing within the selected ECG strip. If the QT tab from the header menu is not open, all the drawings will be colored green. With QT tab not open and magnification level 2 or above, the values within the Focus Chart now show both QT and QTc values.

If the QT tab from the header menu is open and the if Plot is selected from the Select Data radio button group, the QTc Calculation (Bazzet, Friderica and Framingham) values can be selected for visualization within the Focus Chart.

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ൽര Figure 53: QT in Focus Chart.

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## 4.7. Edit mode

The edit mode is toggled with a click on the "Edit mode" toggle switch in the monitoring header section (Figure 29).

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 is able to perform editing actions on the list of ECG strips by using drag and drop.

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 54). 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.

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Figure 54: 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 informes the user that the changes in the annotations have been successfully processed (Figure 55).

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Figure 55: 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 similar to the one described in Figure 54 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 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. It asks the doctor if he preferes to save the changes he has made during in Edit mode, exit the Edit mode and continue to the Beats or Episodes sections, or he wishes to cancel his action and stay in the BPM section with the Editing mode enabled (Figure 56).

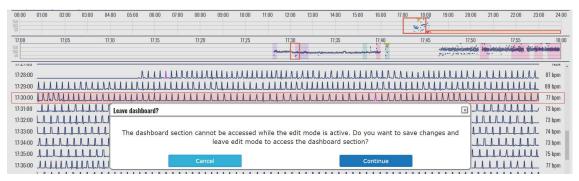


Figure 56: Leaving Monitoring section when Edit mode is enabled prompt window

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 64).

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4:00 July July July July July July July July	switch to edit mode?	ماماساب	73 bpm
	Cancel Continu	e huhululu	75 bpm

Figure 57: Prompt when a user tries to enter Edit mode from Beats or Episodes section

The edit mode supports a drag&drop and right click interaction events. Therefore, the doctors can add, edit and delete episodes directly from the focus chart. The drag&drop features works while having the Shift button pressed down (Figure 58 and Figure 59). 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.

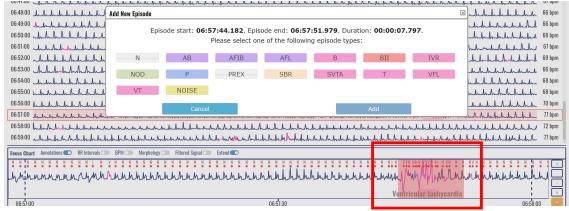


Figure 58: Segment selection for segment editing

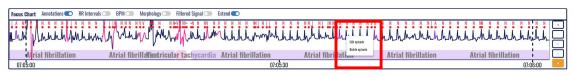


Figure 59: Segment selection with Shift function

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 60).

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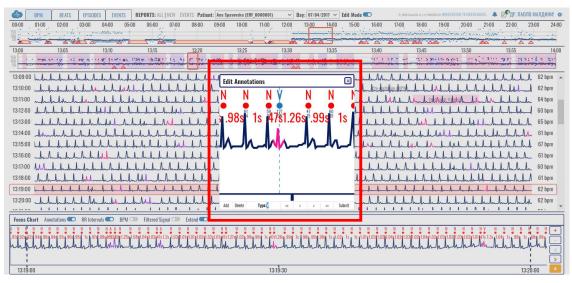


Figure 60: Beat annotation editing

The nearest annotation to the click is marked as 'selected', meaning that 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&drop interaction on the selected annotation. By double click on the selected annotation, the annotation is either repositioned exactly in-between the neighboring annotations or is deleted (the decision to reposition or delete is AI supported for achieving optimal editing).

By double-click on anything but the beat annotations, in 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 neighboring four annotations (Figure 61). When the selected annotation is in optimal position (the neighboring RR intervals result in BPM difference of  $\leq 3$  BPM) the BPM preview values are colored green and are bolded, in contrast to the default blue color of the BPM preview.

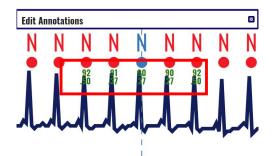


Figure 61: BPM preview

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.

## **4.8. 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 62) 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.

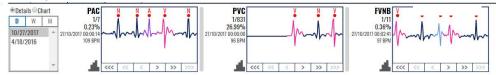


Figure 62: Beats navigator displayed instead of hour selector over the list of ECG strips.

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 63) 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.

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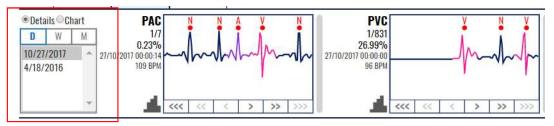


Figure 63: Control section of beats navigator.

The period selector section (left side of control section Figure 63) 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).

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.

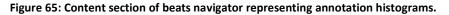
The information domain selector has two radio buttons that form a radio button group and display the options: Details and Chart. When the option "Details" is selected the content section of the beats navigator displays the dashboard of annotated beats (Figure 64) and when the option "Chart" is selected the content section presents the annotation histograms of detected beat types (Figure 65).

The content section of the beats located on the right side of the beats navigator (Figure 64) provides statistical info and quick access to the selected information domain (beat annotations) for a time period selected from the beats control panel.



Figure 64: Content section of beats navigator representing dashboard of annotated beats.

Details Chart	Beat Types	31001								
D W M	PAC =	2480-								
10/27/2017	PVC -	1860-								
4/18/2016	FVNB	1240-								
		620-								
1		0			100			200		
		00	01	02	03	04	05	06	07	(



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## Dashboard of annotated beats

This dashboard displays the annotated beats (Figure 64). When the information domain is set to details, the content section provides information box (Figure 66) for each annotation detected in the selected period.

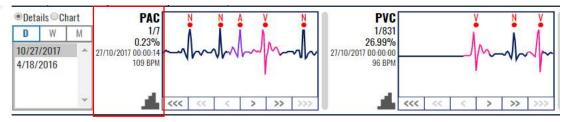


Figure 66: Information box is associated to each annotated beat type.

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;
- 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).

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.

A click in the display box results with opening an extended viewer (explained details in the next sections) in order to enable a better visualization of the detected arrhythmia beat.

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.

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#### Annotation histogram of detected beat types

Beats navigator can present a histogram of annotated beats (Figure 67). The histogram shows the count of occurrences calculated per hour, so you can easily monitor when these detected beats occurred.

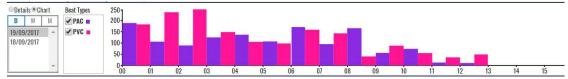


Figure 67: Column bar histogram of annotated beat types in the beats navigator.

A beat type selector (called series Figure 68) 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.

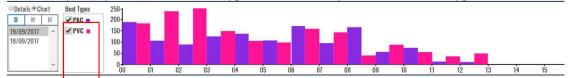


Figure 68: Beat type selector box for histogram of annotated beats in beats navigator.

The histogram is a column view chart and each detected beat type is presented with 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 69) instead of column bar chart (Figure 67). You can choose presentation of the histogram with relative percentages (Figure 70) instead of relative values (Figure 67). Details on controls which toggle the histogram formatting can be found in the monitoring settings section.

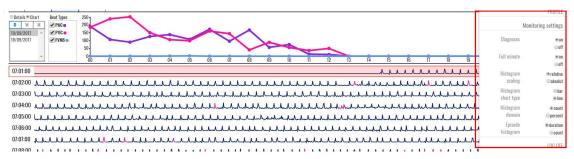


Figure 69: Histogram of detected beat types presented by lines instead of column bars.

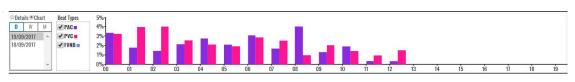


Figure 70: Column bar histogram of annotated beat types with relative values.

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## 4.9. 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 71) 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.

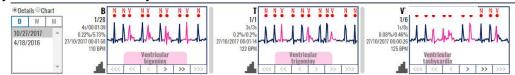


Figure 71: Episodes navigator displayed instead of hour selector or beats navigator over the list of ECG strips.

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 72 and Figure 63) 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.

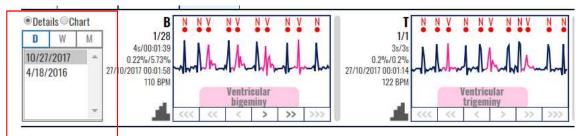


Figure 72: Control section of episodes navigator.

The period selector section (left side in control section Figure 72) 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 73 and Figure 64) and when the option "Chart" is selected the content section presents the histograms of rhythm episodes (Figure 74).

The content section of the episodes located on the right side of the episodes navigator (Figure 73) provides statistical info and quick access to the selected information domain (episode annotations) for a time period selected from the episodes control panel.

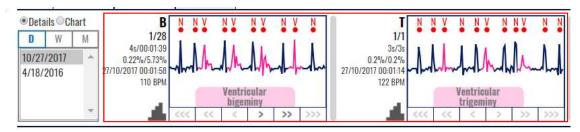


Figure 73: Content section of episodes navigator representing dashboard of annotated episodes.

Details Chart	Episode Types	12581								
D W M	🖉 B 🔳	100s-								
10/27/2017 🔶	✓T =	75s-								
4/18/2016	VT 🔳	50s-								
		25s-								
-		0s	14 14		2204 1022				-	
		00	01	02	03	04	05	06	07	0

Figure 74: 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 75) by clicking on the corresponding radio button.

Details Chart     D     W     M     19/09/2017	AFIB N N N Y N 1/70 09:01:05/00:35:50	BN N YN Y N Y N N N 1/3 2209: 0%001%	SBR N & A & N N N N 1/1 1-/15 0%/0%		T N N V N N V N N 1/1 505% 001% 1	VT 1/23 25/435 05:01076
18/09/2017	E/05/2017 19:14:40 Why Mahalum Manual Manu Manual Manual	18/09/2017 07:54:03 126 BPM	18/09/2017 23:16:01		18/09/2017 09:29:05	18/09/2017 07:44:47 108 BPM
-	Atrial fibrillation	Ventricular bigeniov	Itrial         Superventricular         Atrial           illabindpehydirrhythmia         fibrillation           <<<<<<<<<<><<<<>>>>>>>>>>>>>	Singusventricular         Atrial           adychydiorhythmia         fibrillation           <<<<<<<<<><<>>>>>>>>>>>>>>>>	Ventricular           trigeniny           <<<<<<>>>>>>>>>>>>>>>>>>>>>>	<u> </u>

#### Figure 75: 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).

Right from the information box there is:

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

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## Histogram of rhythm episodes

Dashboard can display a histogram of detected rhythm episodes (Figure 76) by clicking on "Chart" radio button from the information domain selector.

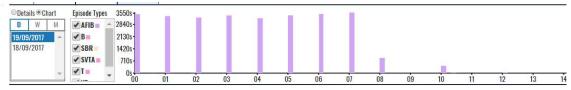


Figure 76: Histogram of detected rhythm episodes.

A column view of the episode histogram is displayed by default. You can select another type of presentation by the settings option, such as line chart.

The x-axis features time intervals, whilst the y-axis features the number of episode 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.

## **4.10. 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;

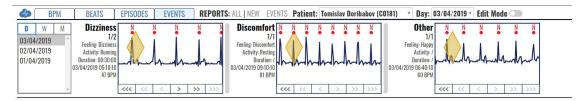


Figure 77: Content section of events navigator.

#### **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.

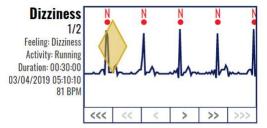


Figure 78: Dashboard of event.

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:

  - $\circ$  << the first event in the analyzed period,
  - $\circ$  < the previous event in the analyzed period,
  - $\circ$  > the next event in the analyzed period,
  - $\circ >>$  the last event in the analyzed period, and
  - $\circ$  >>> 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.

# 4.11. QT

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

The QT section is shown when the tab pill "QT" is selected from the monitoring header menu. The QT 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. 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

The control section 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 (three radio buttons that form a group) located on the right side of the control section and is used to determine whether the content section will contain details about Overall, Plot or Alerts as Selected Data.

## **Overall dashboard**

When Overall is selected form the Select Data radio button group (default option), the content section is being divided into two segment:

- Overall statistics table that contains the following values:
  - QRS Avg (ms)
  - QT Avg (ms)
  - QTc Bazzet Avg (ms)
  - QTc Friderica Avg (ms)
  - QTc Framingham Avg (ms)
- QT/QTc Min and Max values which can be the total of the following eight:
  - o QT Max
  - o QT Min
  - QTc Max Bazzet
  - QTc Min Bazzet
  - QTc Max Friderica
  - QTc Min Friderica
  - QTc Max Framingham
  - QTc Min Framingham

When clicked one of the provided QT/QTc Min/Max segment, that segment is being opened in focus chart that gives detailed overview of it. For each available segment there are the following information:

- 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

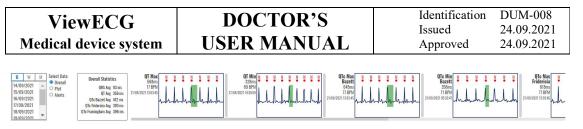


Figure 79: Overall dashboard.

## **Plot dashboard**

When Plot is selected form the Select Data radio button group, the control section now has an additional radio button group that can be used to switch between QTc Calculations:

- Bazzet,
- Friderica, and
- Framingham.

Within the content section there are two plots available:

- A 24-hour plot that shows one preselected hour which is chosen by default by the availability of data. This plot is clickable and contains navigation between the ECG strips
- Second plot that shows the selected QTc calculation can be one of the following: Bazzet, Friderica or Framingham.

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.

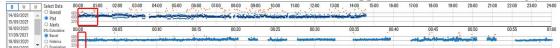


Figure 80: Plot dashboard.

## **Alerts dashboard**

When Alerts is selected from Select Data radio button group, the content section now provides visualization of short and long QTc values and can be a total of six visualizations:

- Bazzet QTc Long Intervals
- Bazzet QTc Short Intervals
- Friderica QTc Long Intervals
- Friderica QTc Short Intervals
- Framingham QTc Long Intervals
- Framingham QTc Short Intervals

For navigations there are available six buttons, four are the ordinary next/previous interval, first/last interval and also there are two buttons that have the function to delete the current interval and move to the next/previous one.

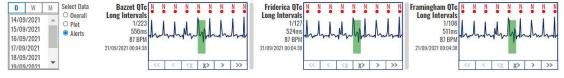


Figure 81: Alerts dashboard.

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## 4.12. Extended Viewer

An extended viewer (Figure 82) can be displayed by clicking on a display box of annotated beats or detected rhythm episodes when beats or episodes info is analyzed.

The annotation visualization box in the beat annotation box from the content section acts as link to an ECG strip where the annotation is located. Upon click, the list of ECG strips and the focus chart in the monitoring are replaced by a pop-up window. The visualization window duration matches the duration of the signal in the focus chart section. The popup window, apart from containing the ECG signal visualization window, has a header on its own. The window header has a timestamp of the annotation, selection duration information (if any), segment duration information, tooltip information, group of buttons to determine the detection type, add to report and close window button.

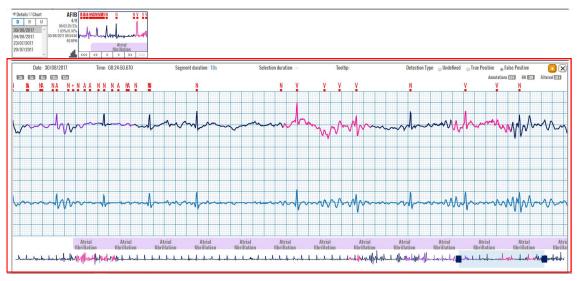


Figure 82: Extended viewer of annotated beats and detected rhythm episodes.

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

The episode visualization box in the annotation box from the content section acts as link to an ECG strip where the episode is located. Upon click, the list of ECG strips and the focus chart in the monitoring are replaced by a pop-up window. The visualization window duration matches the duration of the signal in the focus chart section. The popup window, apart from containing the visualization window, has a header on its own. The window header has a timestamp of the episode, episode duration information, selection duration information (if any), segment duration information, tooltip information and close window button.

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

There is an "add to report" button (Figure 83) 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.

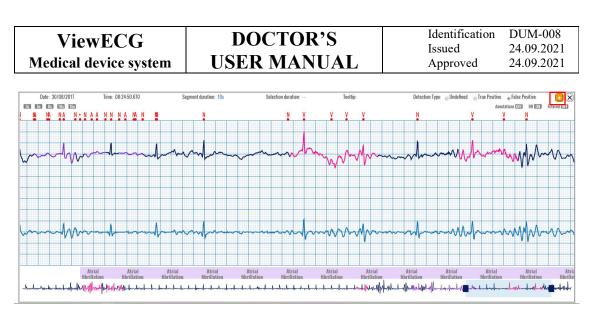


Figure 83: "Add to report" button on the extended viewer.

The extended viewer also allows the doctor to modify the detection type of the episodes detected automatically by the software using three radio buttons that are located in the window header. The default value that is selected for a detected episode or beat type is marked as "Undefined". This specifies that the information visible on the screen have been provided by the software and their validity hasn't been confirmed or modified by the doctor. There is the option to mark the detected type in the extended viewer as a True Positive value, meaning that the doctor confirms that the software has correctly detected the type, or a False Positive value which marks that the doctor considers the episode incorrectly detected by the software. Upon change in selection between Undefined, True Positive or False Positive the detection type is changed and the changes are saved (Figure 84).

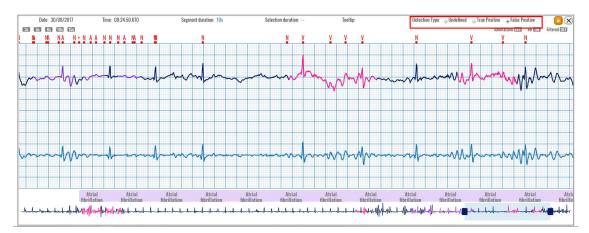


Figure 84: Detection type options of the extended viewer

If the episode shown in the extended viewer is an episode provided by the doctor using the editing mode from the monitoring section (Section 4), the episode will automatically be marked as a False Negative episode and the doctor wouldn't be able to change the detection type (Figure 85).



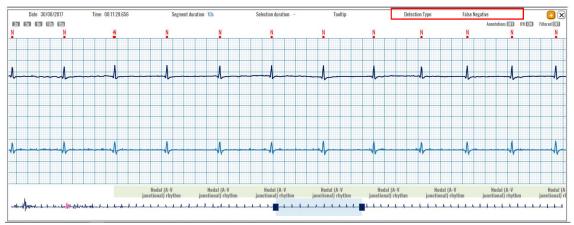


Figure 85: Detection type of a user defined episode

# 4.13. 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.

	BPM	BEATS	EPISODES	EVENTS	REPO	RTS: ALL   NI	EW EVENTS	Patient:	Tomislav De	ribat
00:00	01:00	02:00	03:00	<mark>04:00</mark>	05:00	06:00	07:00	08:00	09:00	10
	01:00	02:00	03:00	04:00	05:00	06:00	0/:00	08:00	09:00	

Figure 86: 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.

<b>4</b>		BEATS 02:00	EPISODES 03:00	EVENTS 04:00	<b>REPORT</b> 05:00	06:00	W EVENTS	Patient: 08:00	Tomislav Do 09:00	riba 1	localhost:44330 says Please enter annotation order number	P	15:00	16:00	17:00	© 2020 VIEWECG 18:00
150 100 50											45 OK Cancel					
06:00 150 100 50		06:05		06:10		06;15		06:20		U	0;20 00;30 00;	55		06:40		06:45
11010121	¹⁰²⁴³⁰⁰ hhaddaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa															
												h	nhh	hhll hhh	hhh	hhh

Figure 87: Navigation to specific beat order number

# 5. How to create and edit a report

## 5.1. Create a report

## Access the report

🗞 BPM BEATS EPISODES EVENTS REPORTS: ALL I NEW EVENTS Patient: Ana Spasorska (EBF_0000001) 🔍 Day: (27/06/2021 🗸 Edit Mode 🗇 « 2019 Indeat alla revenue 🗳 P. ПАОЛО МАЛДИНИ									
	A	BPM	BEATS	EPISODES	EVENTS	REPORTS: ALL   NEW EVENTS Patient: Ana Spasovska (ERF_0000001)	✓ Day: 27/06/2021 ✓ Edit Mode ○	© 2020 ViewEDS v1.1.3. POWERED	🕰 др. паоло малдини! 🔅

#### Figure 88: Monitoring page header.

A report is created by clicking the "NEW" text link in the monitoring page header (Figure 88). After the report creation page is accessed, the doctor can adjust the measurement period and set a preferred information.

## **Report Header**



# The standard application header is located above the custom report header (Figure 89). 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**

SUREMENT PERIOD	20/	11/2	016	TO	21	/11/2	016
-	**		Nove	mber	2016		>>
	Mo	Tu	We	Th	Fr	Sa	Su
	31	1	2	3	4	5	6
	7	8	9	10	11	12	13
	14	15	16	17	18	19	20
R	21	22	23	24	25	26	27
h	28	29	30	1	2	3	4
	5	6	7	8	9	10	11

Figure 90: Measurement period selection.

The monitoring period section (Figure 90) 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 90 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 91).

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ViewECG UPLOAD FILES CREATE PATIENT CO	MPLETED REPORTS	*	DEMO DOCTOR! 🌣

REPORT FOR T. MERCURY MONITOR REPORTS EVENTS

#### Figure 91: Single day measurement.

ON 10/27/2017

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 92: 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	<b>Age</b> 69	Pacemaker No	
Sex Male	Height 180 cm	Medications	
Address 588 Hoffman Avenue	Weight 50 kg	Indications	

#### Figure 93: Patient details section.

The patient details sections (Figure 93) 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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## **5.2.** Summary Information

The summary section (Figure 94) 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

Summary mormation						
GENER	AL INFORMATION		HEART RATE	PAUSES AND	DABERRANT BEATS	
Analyzed Beats	2753	Min HR-4	80 BPM at 27.10.2017 00:13:55	SA Total	0	
<b>Total Recording Duration</b>	00:28:51	Max HR-4	153 BPM at 27.10.2017 00:13:54	Maximum SA	1	
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 - F	REQUENCY DOMAIN	HR	V - 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 a1	0.33	
pNN50	0 %	HF/LF	0.156	DFA a2	1	
rMSSD	17 ms					
VENTRI	ICULAR ECTOPIES	SUPRAVE	NTRICULAR 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	1	Longest SV-Run	1	Max HR	160 BPM at 27.10.2017 00:13:55	
Min HR Long V-Run	1	Min HR Long SV-Run	1			
Max HR Long V-Run	1	Max HR Long SV-Run	1			
VE's per 1000	1	SVE's per 1000	0			
VE's per Hour	6	SVE's per Hour	0			

Figure 94: 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  $\alpha$ 1; and
- DFA α2.

#### 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  $(3 \le n < 6)$  Number of short runs of Ventricular beats
- Long V-Run Total  $(n \ge 6)$  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  $(3 \le n < 6)$  Number of short runs of SupraVentricular beats
- Long SV-Run Total  $(n \ge 6)$  Number of long runs of SupraVentricular beats
- Longest SV-Run the longest number of successive supraventricular ectopy beets 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.

## 5.3. 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 log₁₀n(beats) on the x-axis and the log₁₀F(n) on the y-axis.

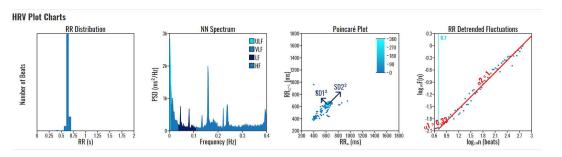


Figure 95: HRV Plot Charts

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# 5.4. 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 96).



Figure 96: 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).

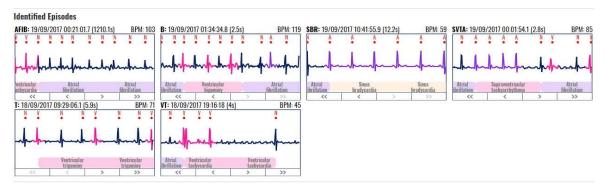
The annotation abbreviation and the annotation ECG strip have as tooltip information on mouse over with the full name of the annotation. A navigation button can be inactive in case such annotation does not exist. In case the content section width is not sufficient to fit all annotation information boxes, 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 97), 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 97: 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.

# 5.5. Histograms and Selected ECG Strips

## Significant Histograms

The report contains a section with significant histograms displayed (Figure 98).

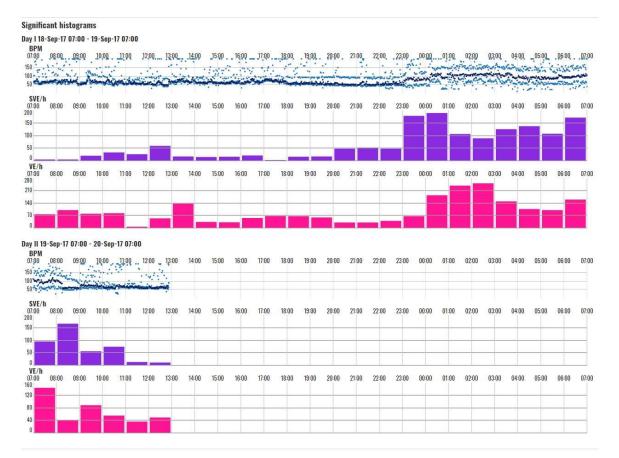


Figure 98: Significant histograms presented in the report.

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 99). 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 99: 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 100: 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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# 5.6. Report edit

Doctor's report can be accessed to edit certain specifications (Figure 101). 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 101: 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≤n<6);
- Long V-Run Total ( $n\geq 6$ );
- Longest V-;
- Min HR V-Run;

- 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  $(3 \le n < 6)$ ;
- Long SV-Run Total  $(n \ge 6)$ ;
- 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 102). A confirmation for deletion is required (Figure 103)

	VENTRICULAR TACHYCARDIA	
Number of episodes		7
Total duration		17.5s (0.03%)
Longest duration	3.1s at 20.	11.2016 18:04:00
Min HR	29 BPM at 20	11.2016 19:07:33
Max HR	97 BPM at 20.	11.2016 21:28:42

### Figure 102: Delete button.

Delete Episode Statistics	
Are you sure you want to	remove the statistics on VT?
Cancel	Remove

Figure 103: Confirmation for deletion of episode statistics.

# 5.7. Writing Opinion and File Management

# Opinion

The report opinion has default preset template in the following format (Figure 104):

"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>"

Jpinion	
The total recording time is 01:33:22. The basic rhythm is atrial fibrillation. Heart rate ranced from 56 bom at 27.06.2021 09:31:44, to 183 bom at 27.06.2021 09:40:10, while the mean value is 99 bom.	
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.	
	1
Discard	Save Save PDF Print Complete

Figure 104: 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 105).

Opinion	
The total recording time is 01-33-22. The basic rhythm is atrial fibrillation. Heart rate ranged from 66 Jppm at 27.06.2021 09:31-44, to 183 Jppm at 27.06.2021 09:40-10, while the mean value is 99 Jppm. No pauses were detected. Overall, there were 16 PACs and 271 PVCs found. There were 256 poincides of atrial fibrillaton. 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.	
	1
Discard	Save Save PDF Print Complete

Figure 105: 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 106).



Figure 106: Print button to activate the printing dialogue.

The report dialogue form (Figure 107) 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).

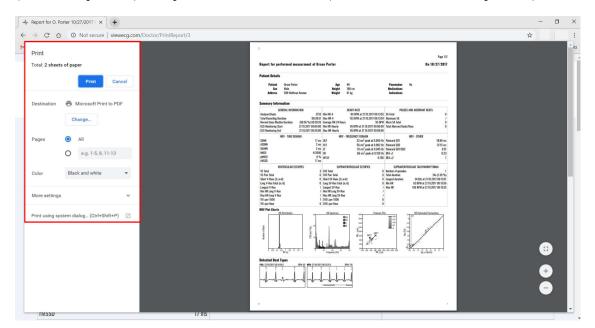


Figure 107: Print dialogue form.

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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		Report Date: 15/10/2020				
Automated Report for A. Spasovska			<b>On 27</b> /	06/2021		
Patient Details						
Patient Sex	Ana Spasovska Female	Age Height	30 170 cm	Pacemaker Medications	No	

#### Figure 108: Printed report sample header.

55 kg

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

• Logo;

Address

• Page number indicator;

AN VIEWERG THE PHYSICIAN MUST REVIEW THE REPORT DATA

588 Hoffman Avenue

- 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.

Weight

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

Papart Date: 10/10/2020 Page 1/2

Indications

r innovation

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

Figure 109: Printed report sample footer.

# 6. How to perform clinical review operations?

When a doctor is registered that he also works as a freelancer (see Settings sections) he is able to see the clinical review section on the doctor's homepage.

The clinical review section enables the freelance doctor to generate reports for patients that have explicitly asked for an expert opinion.

The clinical review section can be entered by clicking on the clock icon that appears in the main header when the doctor is a freelancer. The icon has a badge that displays an integer number and marks the number of current report requests from patients (Figure 110).

	🌲 🚺 🖉 DR. PAOLO M.! 🔅

Figure 110: Clinical review in main header

When the user clicks the icon, a list of all patients that require an expert's opinion about the recorded ECG is displayed with the heading of "Freelancer dashboard".

# Freelancer dashboard

The freelancer dashboard is visually divided into two columns. The left column displays a summary of the number of urgent reports that are waiting for processing at the moment, and a summary of the total reports that need processing at the given moment.

Siewecg upload files create patient completed reports	🌲 🙆 🖉 doctor innovation: 🌣
Freelancer dashboard	Reports history
O URGENT report are waiting for processing at the moment!	Show 10 ¢ entries Search:
	Date 17 Status 11
O report are waiting for processing at the moment!	No data available in table
	Showing 0 to 0 of 0 entries

Figure 111: Freelance dashboard

The right side presents a table of report requests with the date and the status of urgency as table columns. The clinician chooses a patient and opens the monitoring page with a doctor's role and writes the report. When the doctor completes the report, it is added to the list of completed reports to doctor and submitted to the patient.

# 7. How to perform software validation?

The doctor that has the special role of software validator can use the tools for software validation.

The software validator is a separate user role that is designed to ensure that the ViewECG platform is secure and the results are reliable.

# **Initial page**

The initial page is displayed when user logs in using the standard log in functions described in Register and login section (Figure 112).

The initial page displays a form for file uploads and instructions on how the doctor is to use the validator.

In the header section it has the "VALIDATIONS" link that takes the user to a list of all the saved validations (described in detail in Saved Validations bellow).

Description of the second seco	ONS	🐥 SOFTWARE VALIDA	FOR! 1
Software validation	ant mini maa maaa ay to		
Time to upload file depends on t ECG Data Format	Text ECG file	<ul> <li>Step 1: Upload source ECG files. Use one of the formats available:</li> </ul>	
Sampling Rate (Hz)	128	<ul> <li>Text EGF File: Text formal of data where all beats are in raw txt file. Each beat is in new line.</li> <li>MIT BH DAT 16: Official Mit BH File format with 2 byte samples.</li> <li>MIT BH DAT 112: Official Mit BH File format with calculated and 12 bit samples.</li> </ul>	
Sampling resolution (Beats)	10	<ul> <li>MIT BIH DAT 212: Official Mit BiH file format with two channels and 12 bit samples.</li> <li>Step 2: Start processing files. All uploaded files will be send for processing. This can take a while if files are large</li> </ul>	a or lot
Files	Choose Files No file chosen You can select multiple files	of files are uploadeterned. • Step 3: Opload effect. for uploading reference files. You can upload annotation (ann) reference files for each uploaded source file. Tw	o ways ones.
		For one by one use the upload control placed next to each source file. For multiple use the upload control bellow	El a

Figure 112: Software validator initial page

The instructions are as follows:

"

- Step 1: Upload source ECG files. Use one of the formats available:
  - **Text ECG File:** Text format of data where all beats are in raw txt file. Each beat is in new line.
  - MIT BIH DAT 16: Official Mit BIH file format with 2 byte samples.
  - **MIT BIH DAT 112:** Offical Mit BIH file format with one channel and 12 bit samples.
  - **MIT BIH DAT 212:** Offical Mit BIH file format with two channels and 12 bit samples.
- Step 2: Start processing files. All uploaded files will be send for processing. This can take a while if files are large or lot of files are uploaded.
- Step 3: Upload reference files. You can upload annotation (.ann) reference files for each uploaded source file. Two ways for uploading reference files are available. Upload reference files one by one or upload multiple reference files at ones. For one by one use the upload control placed next to each source file. For multiple use the upload control bellow the files in total row.

**IMPORTANT:** All reference annotation files must have same name like the source file, but with .ann as extension.

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- Step 4: Save results. Add name and save results if you want to use them in future.
- Use the options to download processed file's annotations, export results in excel, remove files or upload more files for evaluation.
- Performance evaluation is realized according to IEC60601-2-47 and EC57.

"

The first step the user needs to do is click on **Choose Files** button and choose one or multiple files for upload with the file extension **.ecg**. The user also needs to input the sampling rate and the sampling resolution of the files scheduled for uploading. After the user has finished these steps he needs to start file upload by clicking the "Upload ECG files" button.

# Upload more files to the collection

After the file or files have been uploaded the screen changes so the user sees the upload files and their status in a table format and he is able to upload more files to the same collection (Figure 113).

When the user uploads all the files he wants, he needs to press the Start processing button to start processing the files.

Jpload new ECG files to the same collec Files Choose Files No file chos You can select multiple files	-	plead more files	<ul> <li>Step 1: Upload source ECB files. Use one of the formats available:         <ul> <li>Text ECG File: Text format of data where all beads are in raw tot. file. Each beat is in new line.</li> <li>MIT BHI DAT 16: Official MIR BHI the format with 2 byte samples.</li> <li>MIT BHI DAT 12: Official MIR BHI the format with new dhamel and 12 bit samples.</li> <li>MIT BHI DAT 12: Official MIR BHI the format with new thanels and 12 bit samples.</li> <li>MIT BHI DAT 12: Official MIR BHI the format with new dhamels and 12 bit samples.</li> </ul> </li> <li>Step 2: Start processing files. All uploaded these will be send for processing. This can take a while if files are large or lot of files are uploaded.</li> <li>Step 3: Upload reference files, you can upload ramotabine (anni) reference files for each uploaded source file. Two ways for uploading reference files are available. Upload reference files one by one or upload multiple reference files are upload entrol below the files are upload control below the files</li> </ul>
File		Status	
200.ecg 🗙		Uploaded	

Figure 113: Upload more files to the same collection

# **Reference files upload**

After the user has processed the files he had uploaded the files and processed them a table is displayed on the screen that allows the user to upload reference files to the uploaded ecg files and perform the validation of the software for every file and the one compared with it (Figure 114).

The table has the following columns:

- File displays a clickable link of the file name together with the file extension. Each link has a red X sign next to it that if clicked excludes the file from the collection.
- Status Available status lines are: Uploaded, Processed, Reference file compared
- Annotations A link that allows the user to download the annotations from the source files that the system has produced.
- Upload reference file a file chooser input element to choose a reference file to upload. An "Upload" action link for the file chosen in the corresponding table row. Once the Upload link is clicked the evaluation results are displayed or modified.
- Detected group that groups the Duration value, the QRS, VEB and SVEB for the source file
- Reference group that groups the Duration value, the QRS, VEB and SVEB for the reference file

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The table also displays a table summary row that shows the total number of files in the current collection, a zip file with all the annotations for download, a file upload button that allows the user to upload multiple reference files at once, an "Upload reference files" link that starts the files upload, and a summary value for the Duration, QRS, VEB and SVEB first from the source than from the reference files.

					Detected			Reference			
File	Status	Annotations	Upload reference file		Duration	QRS	VEB	SVEB	QRS	VEB	SVEB
223.ecg 🗙	Reference file compared	Download	Choose File No file chosen	Upload	30m:05s	2658	419	0	2605	419	56
202.ecg 🗙	Processed	Download	Choose File No file chosen	Upload	30m:05s	2145	39	0			
Total	2 Files		Choose Files No file chosen You can select multiple files	Upload reference files	01h:00m:11s	4803	458	0	2605	419	56

#### Figure 114: Upload reference files

# File monitoring

When the user has the role of software validator, he is able to see results of the comparison of the detected beats and episodes in one file, with those from a reference annotation file. This function enables the users to verify the correctness and reliability of the software.

As a part of the possibilities offered to the software validator user, there is a monitoring function enabled where the user sees files in comparable fashion. This function is activated by clicking on the filename from the Reference file upload table described previously. After the processing of each file in the collection, the filename becomes a clickable link that allows the user in the role software validator to click and see the ECG of the file (see Reference files upload for more detail).

This monitoring feature has similar look as the one described in Main monitoring page with the following differences (Figure 115):

- Only the BPM section and the standard notification, user and settings part from the header menu options are left, all the other options are removed.
- On the hour navigator there are marks both on the top and on the bottom of the navigator, instead of only those in the bottom. The marks on the top demonstrate the marks from the file processed by the software, and those in the bottom are those form the reference files.
- The focus chart shows two lines of annotations and episode diagnosis. The first line represents the detected episodes and annotations by the software and is displayed above the ecg signal, and the second line of shows the annotations and episodes from the reference files and is displayed below the ecg signal drawn in the focus chart.
- The add to report button is also removed, as well as all the focus chart toggle options other than the Grid option.
- A small portion on the left side of the focus chart is dedicated to write the labels Detected and Reference in two separate lines to mark that one line of annotations and episodes are those detected by the software and the other line are those from the reference file.

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da RPM			VATION 🌲 SOFTWARE VALIDATOR! 🗢
	200 08:00 09:00 10:00 11:00 12:00 13:00 14:00 15:00	C 2019 ECGALERT (1.0.0. POWERED BY INNO 16:00 17:00 18:00 19:00 20:00 21	00 22:00 23:00 24:00
		1000 1000 1000 1000 10	
	00:20 00:25 00:30 00:35	00:40 00:45 00:50	00:55 01:00
00:00:00 and hard hard hard the of th		man have been and the second and the second	And Inderstand 75 bpm
00:01:00 And marked and the and the and the contract of the co	a had	hite hat he had been here here here here here here here h	73 bpm
00:02:00		· · · · · · · · · · · · · · · · · · ·	A Spm
00:03:00 Augustu hugust hube had a find and here had	And Marken Marked and a stand of the stand o		-tutututututut 73 bpm
00:04:00		real and a contraction	
00:05:00 month month have been and the such have	udub dud han been been been been been have been been been been been been been be	had a	Andreander And 73 bpm
00:06:00 and	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	1 A A A A A A A A A A A A A A A A A A A
00:07:00 And have been and have been and have	Anderson and Andreas and	inful have a first and a first and a start and a start and a start a start a start a start a start a start a st	- 72 bpm
00:00:00 manage and a construction of the cons	********		Atrial fibrillation 74 bpm
00-09-00 Arrist fibrillation Sings bradycaddial fibrillation	Atrial fibrillation	Arrial fibrillation	Atrial fibrillation 78 bpm
00:10:00 Atrial fibrillation	Atrial fibrillation Atrial fibrillation Atrial fibrillation Atrial fibrillation	al fibrillation Atrial	fibrillation 78 bpm
00:11:00 Atrial fibrillation	Atrial fibrillation Atrial fibrillation Atrial fibrillation Atrial fibrillation Atrial fibrillation	Abrillation	80 bpm
00:12:00 Arial fibrillation Arial fibrillation Atrial fibri	illation Atrial fibrillications werdtrichter Bahrand mit Mathematiker ausgehören bei Vitarial fibrillation	Sinus bradycard anticipation of the state of	Atrial fibrillation
Focus Chart Grid			[10mm/mV][25mm/sec] [125Hz]
Detected: Atrial fibrillation Atrial fibrillation	Atria fibrillation Atrial fibrillation Atrial fibrillation	sinus bradycardia	Atrial fibrillation
			,
Reference:		•	
	Atrial fibrillation Atrial fibrillation Nodal (	A-V junctional) rhythm Nodal (A-V junctional) rhyth	

Figure 115: Comparable monitoring screen

00:09:10

# **Evaluation results**

00:09:00

The software validator analyses the files that are being previously processed and displays the evaluation analysis. A user can save a specific analysis giving it a name, and then see the results from that analysis at a later date from the table of all validations. Even if the user doesn't want to save the results from the file he has processed, after the file processing the evaluation results are still displayed in the evaluation results section that appears bellow the table in Figure 114.

The evaluation results section is divided into 4 subsections. The first is the summary subsection, the second is the Beat detection and classification subsection, the third is the Run to Run analysis and the last is the Episodes subsection.

### **Summary**

This subsection summarizes all the results from the beats, run to run and episodes analysis. The results are the table summary results from the above mentioned subsections that will be explained in the following text.

### **Beat detection and classification**

For every file in the collection the following information are presented in a table: Status, QRS SEN, QRS PPV, V SEN, V PPV, V FPR, SV SEN, SV PPV and SV FPR. The table summary section of the table summarizes the information for all the files in the collection and displays the Total and the Average calculated values in two separate rows (Figure 116).

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Beat detection and classification

File	Status	QRS SEN	QRS PPV	V SEN	V PPV	V FPR	SV SEN	SV PPV	SV FPR
100.ann	OK	100.00%	100. <mark>0</mark> 0%	100.00%	100.00%	0.00%	100.00%	100.00%	0.00%
200.ann	OK	99.73%	99.92%	98.48%	94.77%	2.38%	75.00%	60.00%	0.47%
222.ann	OK	99.84%	100.00%	0.00%	-	0.00%	92.27%	85.04%	3.01%
223.ann	OK	100.00%	100.00%	98.81%	87.53%	2.70%	100.00%	62.92%	1.29%
	Total	99.89%	99.98%	94.99%	92.13%	1.17%	92.81%	81.15%	1.17%
- 1	Average	99.89%	99.98%	74.32%	94.10%	1.27%	91.82%	76.99%	1.19%

Extended evaluation of beat annotations  $\checkmark$ 

#### Figure 116: Beat detection and classification

There is also a "Extended evaluation of beat annotations" that opens a dropdown with tables with more detailed information (Figure 117). Four separate tables are represented.

The first table displays the following information for every file in the collection:

QRS, QTP, QFP, QFN, VTP, VTN, VFP, VFN, SVTP, SVTN, SVFP, SVFN.

The total and average values for the same information are displayed in the table summary.

The second table in similar fashion and formatting displays the following information: NN, NS, NV, NF, NQ, NO, NX, SN, SS, SV, SF, SQ, SO, SX.

The third displays: VN, VS, VV, VF, VQ, VO, VX, FN, FS, FV, FF, FQ, FO, FX.

The fourth table displays: QN, QS, QV, QF, QQ, QO, QX, ON, OS, OV, OF, OQ, XN, XS, XV, XF, XQ.

File	QRS	QTP	QFP	QFN	VTP	VTN	VFP	VFN	SVTP	SVTN	SVFP	SVFN					
100.ann	2273	2273	0	0	1	2272	0	0	33	2240	0	0					
200.ann	2604	2595	2	7	779	1767	43	12	18	2561	12	6					
222.ann	2484	2480	0	4	0	2434	0	46	358	2029	63	30					
223.ann	2605	2605	0	0	414	2127	59	5	56	2516	33	0					
Total	9966	9953	2	11	1194	8600	102	63	465	9346	108	36					
Average	2491.5	2488.25	0.5	2.75	298.5	2150	25.5	15.75	116.25	2336.5	27	9					
File	NN	NS	NV	NF	NQ	NO	NX	SN	SS	SV	SF	SQ	SO	SX			
100.ann	2239	0	0	0	0	0	0	0	33	0	0	0	0	0			
200.ann	1735	12	36	1	0	3	0	1	18	5	0	0	0	0			
222.ann	1986	60	0	0	0	4	0	30	358	0	0	0	0	0			
223.ann	2029	31	59	11	0	0	0	0	56	0	0	0	0	0			
Total	7989	103	95	12	0	7	0	31	465	5	0	0	0	0			
Average	1997.25	25.75	23.75	3	0	1.75	0	7.75	116.25	1.25	0	0	0	0			
File	VN	VS	VV	VF	VQ	VO	VX	FN	FS	FV	FF	FQ	FO	FX			
100.ann	0	0	1	0	0	0	0	0	0	0	0	0	0	0			
200.ann	7	0	779	1	0	4	0	0	0	0	0	0	0	0			
222.ann	43	3	0	0	0	0	0	0	0	0	0	0	0	0			
223.ann	0	2	414	3	0	0	0	0	0	0	0	0	0	0			
Total	50	5	1194	4	0	4	0	0	0	0	0	0	0	0			
Average	12.5	1.25	298.5	1	0	1	0	0	0	0	0	0	0	0			
File	QN	QS	QV	QF	QQ	QO	QX	ON	05	OV	OF	00	XN	XS	XV	XF	XQ
100.ann	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
200.ann	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
222.ann	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
223.ann	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Average	0	0	0	0	0	0	0	0	0	0.5	0	0	0	0	0	0	0

Figure 117: Extended evaluation of beat annotations

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### **Run To Run Analysis**

For every file in the collection the following information are presented in a table: VEB CSe, VEB C+P, VEB SSe, VEB S+P, VEB LSe, VEB L+P, SVEB CSe, SVEB C+P, SVEB SSe, SVEB S+P, SVEB LSe and SVEB L+P. The table summary section of the table summarizes the information for all the files in the collection and displays the Total and the Average calculated values in two separate rows (Figure 118).

File	<b>VEB CSe</b>	VEB C+P	VEB SSe	VEB S+P	VEB LSe	VEB L+P	SVEB CSe	SVEB C+P	SVEB SSe	SVEB S+P	SVEB LSe	SVEB L+P
100.ann	-	-	-	-	-	-	-	-	-	-	-	
200.ann	52.38%	100%	14.29%	50%	-		100%	100%	-	-		
222.ann	-	0%	1.2			÷	80.95%	82.14%	84.85%	91.89%	47.37%	90.91%
223.ann	85.19%	100%	<mark>40</mark> %	100%	100%	100%	12.5%	100%	0%	1		1
Total	65.22%	96.36%	25.00%	90.00%	100.00%	100.00%	52.63%	83.87%	82.35%	91.89%	47.37%	90.91%
Average	68.78%	66.67%	27.14%	75.00%	100.00%	100.00%	64.48%	94.05%	42.42%	91.89%	47.37%	90.91%

### Figure 118: Run to run analysis

There is also a "RTR Extended" that opens a dropdown with tables with more detailed information. Four separate tables are represented (Figure 119).

The first table isplays the following information for every file in the collection:

VEB CTs, VEB CFN, VEB CTp, VEB CFP, VEB STs, VEB SFN, VEB STp, VEB SFP, VEB LTs, VEB LFN, VEB LTp and VEB LFP. The total and average values for the same information are displayed in the table summary.

The second table in similar fashion and formatting displays the following information: SVEB CTs, SVEB CFN, SVEB CTp, SVEB CFP, SVEB STs, SVEB SFN, SVEB SFP, SVEB LTS, SVEB LFN, SVEB LTp and SVEB LFP.

Average	5	4.5	6.5	1.25	7	1.5	8.5	0.75	2.25	2.5	2.5	0.2
Total	20	18	26	5	28	6	34	3	9	10	10	
223.ann	2	14	2	0	0	1	0	0	0	0	0	
222.ann	17	4	23	5	28	5	34	3	9	10	10	
20 <mark>0</mark> .ann	1	0	1	0	0	0	0	0	0	0	0	
100.ann	0	0	0	0	0	0	0	0	0	0	0	
File	SVEB CTs	SVEB CFN	SVEB CTp	SVEB CFP	SVEB STs	SVEB SFN	SVEB STp	SVEB SFP	SVEB LTs	SVEB LFN	SVEB LTp	SVEB LF
Average	11.25	6	13.25	0.5	0.75	2.25	2.25	0.25	0.5	0	2	
Total	45	24	53	2	3	9	9	1	2	0	8	
223.ann	23	4	28	0	2	3	8	0	2	0	8	)
222.ann	0	0	0	2	0	0	0	0	0	0	0	
200.ann	22	20	25	0	1	6	1	1	0	0	0	
100.ann	0	0	0	0	0	0	0	0	0	0	0	
File	VEB CTs	VEB CFN	VEB CTp	VEB CFP	VEB STs	VEB SFN	<b>VEB STp</b>	VEB SFP	VEB LTs	VEB LFN	VEB LTp	VEB LF

### Figure 119: RTR Extended

# **Episodes**

For every AFIB episode present in the collection of files, a table with the AFIB label is displayed. The following information are present in the table: E_SEN, E_PPV, D_SEN, D_PPV, A_SEN and A_PPV for every file in the selection. The Total values are also present for the whole collection as a table summary row.

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There is also a link with the text "Extended evaluation of AFIB" that extends another table with the following information for every file: TPS, TPP, TPA, FNS, FNP, FNA, FPA, LON, LOL, LAN, LAL, RON, ROL, RAN and RAL. It also has a summary row for summary information on all files in total (Figure 120).

Episodes															
AFIB															
File	E_SEN	E_PPV	D_SEN	D_PPV	A_SEN	A_PPV									
100.ann	-	-	-	-	-	-									
200.ann	0.00%		0.00%		0.00%										
222.ann	27.78%	95.83%	10.22%	100.62%	11.76%	96.91%									
223.ann															
220.000															
Total	26.79%			100.62%	11.50%	96.91%									
Total		AFIB 🔨					FPA	LON	LOL	LAN	LAL	RON	ROL	RAN	RAL
Total Extended	26.79% evaluation of	AFIB 🔨	TPA	FNS	FNP	FNA	FPA 0	LON	LOL	LAN O	LAL	RON 0	ROL 0	RAN 0	
Total Extended File	26.79% evaluation of TPS	AFIB AFIB	TPA 0	FNS	FNP 0	FNA 0					LAL 0 2936				RAL 0 0
Total Extended File 100.ann	26.79% evaluation of TPS 0	AFIB AFIB O	<b>TPA</b> 0 0	FNS 0 2	FNP 0 0	FNA 0	0	0	0	0	0	0	0	0	0
Total Extended File 100.ann 200.ann	26.79% evaluation of TPS 0 0	AFIB AFIB O	<b>TPA</b> 0 0 188	<b>FNS</b> 0 2 39	<b>FNP</b> 0 0 1	<b>FNA</b> 0 36 1411	0	0	0 0	0 2	0 2936	0 0	0	0	0

#### Figure 120: Episodes

# Save Results

This subsection represents a form that enables the user to enter a name for the selected collection of files and the results and then Save the form and all result data. This subsection is displayed only when the user creates the collection for the first time. If the user only views a saved collection, the evaluation results will not display the Save Results subsection (more detail available in Saved Validation View section below).

The user can enter the name of the collection and the collection with all the files and a datetime stamp will be saved and displayed in the Validations screen.

# **Saved Validations**

A sorted table of all validations by the logged in user where the date and name column fields are clickable and change the sorting order is displayed when the user clicks on the Validations link in the header menu, next to the company logo.

A table is presented with the following columns:

- Date a date time timestamp when the collection was created
- Name the name given to the file collection.
- Unnamed column in the cells of each row of which there is the action link Delete that allows the user to delete the file collection in the selected row.

A click on the date or the name of the collection leads the doctor to the view of the specific validation (Saved Validation View).

# Saved Validation View

When viewing a saved file collection, collection of files and the evaluation results for those files analyzed are displayed to the user. The screen is same as the one described in Evaluation results with the difference that the Save Results section is removed.

# Data Sets

Software validator contains data sets with patients that can be used for ECG processing. The standard databases available for selection are (Figure 121):

- MIT DB without Paced Rhythm (44 patients)
- <u>MIT DB Total (48 patients)</u>
- AF DB (23 patients only AFIB)
- LTAF DB (84 patients)
- NSR DB (18 patients)
- <u>CU DB (35 patients)</u>
- E DB (90 patients)
- <u>NST DB (12 patients)</u>
- AHA DB (77 patients)

After the selection of the appropriate data set, a list of available patients will be shown for which data can be downloaded (Figure 122).

<b>ViewECG</b> UPLOAD FI	LES VALIDATIONS				SOFTWARE VALIDATOR!
se select database					
DB without Paced Rhythm (44 patients) DB (84 patients) (90 patients)		MIT DB Total (48 patients) NSR DB (18 patients) NST DB (12 patients)		AF DB (23 patients only AFIB) CU DB (35 patients) AHA DB (77 patients)	
ut Support Terms and co	nditions Privacy policy Refun	nd policy Return policy	Prices	c	2020 VIEWECG v1.0.3. POWERED BY INNOVAT
					TECHNOLOG
		Ei	auro 121: Data sots		
		Fi	gure 121: Data sets		
MIT DB with	out Paced Rhythm (44 patients)	Fi	gure 121: Data sets		AF DB (23 patients only AFIB)
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	patients)	Fi	MIT DB Total (48 patients)		
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LTAF DB (84 E DB (90 pat Patients	patients)  ssing Select patients for proc	essing and click on the "Sta	MIT DB Total (48 patients) NSR DB (18 patients) NST DB (12 patients)		CU DB (35 patients)
LTAF DB (84 E DB (90 pat Patients Start proce Patient	ssing Select patients for proc	essing and click on the "Sta Download all	MIT DB Total (48 patients) NSR DB (18 patients) NST DB (12 patients)		CU DB (35 patients)
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LTAF DB (84 E DB (90 path Patients Start proce Patient 118e_6 118e00 118e06 118e12	saling Select patients for proc Select patients for proc Select all C C C C C C C C C C C C C C C C C C	essing and click on the "Sta Download all Download Download Download Download	MIT DB Total (48 patients) NSR DB (18 patients) NST DB (12 patients)		CU DB (35 patients)
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LTAF DB (84 E DB (90 part Patients Start proce Patient 118e_6 118e00 118e06 118e12 118e12 118e18 118e24	ssing Select patients or proceed of the select all of the select a	essing and click on the "Sta Download all Download Download Download Download Download	MIT DB Total (48 patients) NSR DB (18 patients) NST DB (12 patients)		CU DB (35 patients)
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LTAF DB (84 E DB (90 part Patients Start proce Patient 118e_6 118e00 118e06 118e12 118e18 118e24 119e_6 119e00	ssing Select patients for proce Select patients for proce Select all Select	essing and click on the "Sta Download all Download Download Download Download Download Download Download	MIT DB Total (48 patients) NSR DB (18 patients) NST DB (12 patients)		CU DB (35 patients)
LTAF DB (84 E DB (90 part Patients Start proce Patient 118e_6 118e00 118e12 118e18 118e24 119e_6 119e00 119e06	saling Select patients for processing Select patients for processing Control of the select all C	essing and click on the "Sta Download all Download Download Download Download Download Download Download Download	MIT DB Total (48 patients) NSR DB (18 patients) NST DB (12 patients)		CU DB (35 patients)
LTAF DB (84 E DB (90 particular) Patients Start proceedings Patient 118e_06 118e10 118e12 118e18 118e24 118e24 118e26 119e00 119e06 119e12	saling Select patients for processing Select patients for processing Control of the select patients for patients for processing Control of the select patients f	essing and click on the "Sta Download all Download Download Download Download Download Download Download Download	MIT DB Total (48 patients) NSR DB (18 patients) NST DB (12 patients)		CU DB (35 patients)
LTAF DB (84 E DB (90 particular) Patients Start proceed Patient 118e_06 118e100 118e12 118e18 118e24 118e24 119e06	saling Select patients for processing Select patients for processing Control of the select all C	essing and click on the "Sta Download all Download Download Download Download Download Download Download Download	MIT DB Total (48 patients) NSR DB (18 patients) NST DB (12 patients)		CU DB (35 patients)

Figure 122: Patients sets

# 8. How to use the expert functions?

Given that a expert is a registered user, the standard "login" functions explained earlier are used to log in to the web application.

Menu options are:

- Convert ECG to ANN,
- Convert ANN to HRV,
- Episode statistics,
- Download data.

# **Convert ECG to ANN page**

The Convert ECG to ANN page is used to ECG file selection and processing. As a result you will receive an ".ann" file (Figure 123).

When the expert opens the Convert ECG to ANN page, they can select one or multiple ECG files for processing. When the files are processed they will receive an ".ann" file.

<b>WiewECG</b> CONVERT	ECG TO ANN CONVERT ANN TO HRV EPISODE ST/	FISTICS DOWNLOAD DATA	🌲 ЕКСПЕРТ ДОКТОР! 🙍
Convert ECG to ANN Time to upload file depends on	he amount and size of the files. Please be patient.		
File	Choose Files 4 files If the sample rate is not 125Hz, it will be resampled to 125Hz.		
	Start transferring		
About Support Terms and c	onditions Privacy policy Refund policy Retur	policy Prices	© 2020 VIEWECG v1.0.3. POWERED BY INNOVATION Technologies

Figure 123: Convert ECG to ANN

# **Convert ANN to HRV page**

The Convert ANN to HRV page is used to ANN file selection and processing. As a result you will receive a ".hrv" file (Figure 124).

When the expert opens the Convert ANN to HRV page, they can select an ANN file for processing and set "Start Date" and "Sampling rate" for that file. When the file is processed, they will receive an HRV file and table with HRV results will show up.

ViewE Medical devi		DOCT USER M		Identification Issued Approved	DUM-008 24.09.2021 24.09.2021
NiewECG CONVERT	ECG TO ANN CONVERT ANN TO H	RV EPISODE STATISTICS DOV	/NLOAD DATA		• ЕКСПЕРТ ДОКТОР! 🌣
Convert ANN to HRV Time to upload file depends on t	he amount and size of the files. P	lease be patient.			
start date	14/02/2020	=			
Sampling Rate	125				
General i	Submit	Н	eart rate	Pauses and aberrant be	ats
Analyzed Beats Total Recording Duration Normal Sinus Rhythm Duration ECG Monitoring Start ECG Monitoring End	1 30s 0s 14.02.2020 00:00:00 14.02.2020 00:00:30	Min HR-4 Max HR-4 Average HR-24 Hours Min HR-Hourly Max HR-Hourly	179 0 BPM at 14.02.2020 00:00:00 BPM 0 BPM at 14.02.2020 00:00:00 0 BPM at 14.02.2020 00:00:00	SA Total Maximum SA Micro SA Total Total Aberrant Beats/Runs	0 / 0 0
	me Domain		equency Domain	HRV - Other	
SDNN ASDNN Sdann NN50 pNN50 rMSSD	/ / / / / / /	ULF VLF LF HF HF/LF	0 0 0 NaN		
ownload file					
bout Support Terms and co	onditions Privacy policy Refu	nd policy Return policy Prio	es	© 2020 VIEWECG v	1.0.3. POWERED BY INNOVAT TECHNOLOG

Figure 124: Convert ANN to HRV

# **Episode statistics page**

The Episode statistics page is used to ZIP file selection and processing. As a result you will receive a ZIP file with results (Figure 125).

When the expert opens the Episode statistics page, they can select a ZIP file for processing and set "Sample rate" for that file. When the file is processed, they will receive a ZIP file with results.

4	ViewEC	<b>G</b> CONVERT EC	G TO ANN CONVERT A	NN TO HRV EPIS	ODE STATISTICS	DOWNLO	ID DATA		<b>експерт</b> доктор!	٥
Data Time to		e depends on the	amount and size of th	e files. Please be	p <mark>atient</mark> .					
		File	Choose File No file chose	1						
		Sample rate	125 Start							
About	Support	Terms and cond	ditions Privacy policy	r Refund policy	Return policy	Prices		© 2020 VIEWEC	G v1.0.3. POWERED BY INNO Technol	



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Medical device system	<b>USER MANUAL</b>	Approved	24.09.2021

### **Download data page**

The Download data page is used for selection of patients and downloading their data (Figure 126).

When the expert opens the Download data page, they will see a table with all patients. They can click on the "download" link for specific patient and receive a zip file with all data for that patient.

I VIEWECG CONVERT ECG TO ANN CONVERT ANN TO HRV EPISODE STATISTICS DOWNLOAD DATA	ДОКТОР! 💠
Download data	
The download for patients with lot of data can take few minutes. Please be patient.	
Show 10 - entries Search:	
Code	
DCP_00151	Download
DCP_00150	Download
DCP_00149	Download
DCP_00148	Download
DCP_00147	Download
DCP_00146	Download
DCP_00145	Download
DCP_00144	Download
DEP_00143	Download
DCP_00142	Download
1 2 3 4 5 3	1 Next Last
About Support Terms and conditions Privacy policy Refund policy Return policy Prices © 2020 VIEWECG v1.0.3. POWE	RED BY INNOVATION TECHNOLOGIE

Figure 126: Download data

# 9. How to use the research functions?

Given that a researcher is a registered user, the standard "login" functions explained earlier are used to log in to the web application. The researcher should see a list of all patients by diabetes type. They can select patient and download data. When the researcher click on the code of specific patient in the list, a file with data for that patient should be downloaded.

ViewECG Medical device system							Identification Issued Approved	DUM-008 24.09.2021 24.09.2021
📣 Viewl								RESEARCHER USER! 🌣
Patients AC	by diabete DE	s type AA	AB	CD	CE	DD		
C0213	DCP_00045	C0189	C0196	C0183	DCP_00048	DCP_00060		
27.01.2020	27.01.2020	27.01.2020	27.01.2020	27.01.2020	27.01.2020	27.01.2020		
DCP_00004	C0202	C0206	C0256	C0272	DCP_00043			
27.01.2020	27.01.2020	27.01.2020	27.01.2020	27.01.2020	27.01.2020			

Figure	127: Researcher	function

#### DCP_00004 27.01.2020 CO2O2 27.01.2020 CO2O6 27.01.2020 DCP_00007 DCP_00059 C0245 27.01.2020

DCP_00119

04.02.2020

DCP_00108

04.02.2020

27.01.2020

C0182

27.01.2020

C0236

27.01.2020

C0228

27.01.2020

C0163

27.01.2020

DCP_00009

27.01.2020

C0250

27.01.2020

NC0204

27.01.2020

C0198

27.01.2020

C0215

29.01.2020

27.01.2020

DCP_00018

27.01.2020

DCP_00036

27.01.2020

C0190

27.01.2020

DCP_00046

27.01.2020

DCP_00042

30.01.2020

C0177

21.01.2020

NC0208

27.01.2020

C0186

27.01.2020

DCP_00055

04.02.2020

C0207

27.01.2020

C0209

27.01.2020

DCP_00066

27.01.2020

DCP_00006

27.01.2020

C0257

27.01.2020

C0176

27.01.2020

C0235

27.01.2020

C0216

27.01.2020

C0193

27.01.2020

C0252

27.01.2020

DCP_00010

27.01.2020

DCP_00050

27.01.2020

DCP_00034

27.01.2020

NC0165

27.01.2020

DCP_00054

27.01.2020

C0270

27.01.2020

DCP_00019

27.01.2020

C0229

27.01.2020

DCP_00029

27.01.2020

DCP_00035

27.01.2020

DCP_00040

27.01.2020

	DCP_00114	C0263	C0200		
	31.01.2020	27.01.2020	27.01.2020		
		C0218	C0253		
		27.01.2020	21.01 2020		
* Known diabetes			* Mea	asured diabetes	
A. No diabetes mellitus in the past, or abu B. Regulated with diet C. Regulated with medication D. Regulated with insulin	normal glucose levels		B. P C. N D. K	lormal – HbA1c < 5,6% Prediabetes – HbA1c 5,6-6,5% lewly diagnosed diabetes – HbA1c > 6,5% Gnown diabetes – well controlled – HbA1c < 7%	
			E. K	nown diabetes – uncontrolled – HbA1c > 7%	

Ig

# **10.** 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 128).



Figure 128: 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.

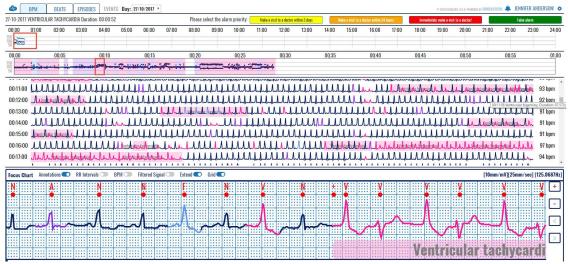


Figure 129: Health-related event monitoring

