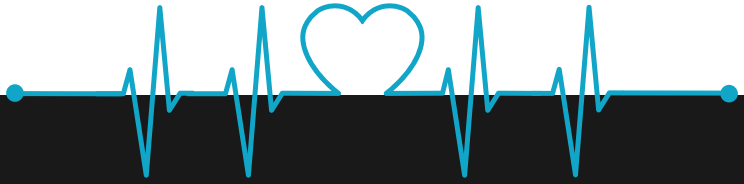
PANONIT D.O.O.
MIROSLAVA ANTIĆA 7, 21000 NOVI SAD

USER MANUAL



FOR MOBILE
ECG DEVICE "CARDIONS E2"

CONTENT OF THE USER MANUAL FOR MOBILE ECG DEVICE "CARDIONS E2"

1. BASIC INFORMATION ABOUT THE MANUFACTURER OF THE MOBILE ECG DEVICE "CARDIONS E2"

FULL NAME	Panonit d.o.o. za sisteme zasnovane na računaru razvoj i proizvodnju u oblasti informacionih tehnologija Novi Sad
SHORT NAME	Panonit d.o.o. Novi Sad
ADDRESS	Miroslava Antića 7, 21000 Novi Sad, Srbija
RESPONSIBLE PERSON	Mladen Sladojević
IDENTIFICATION NUMBER	20276037
VAT NUMBER	104948838
PiO REGISTRATION NUMBER	8227463372
ACTIVITY CODE	6201 - computer programming
COMPANY REGISTRATION DATE	03.04.2007.
VAT	Panonit d.o.o is in the VAT system (resolution number: 325776054)
TELEPHONE	+381 21 420591
FAX	+381 21 544 372
Web site	www.panonit.com
E-mail	info@panonit.com

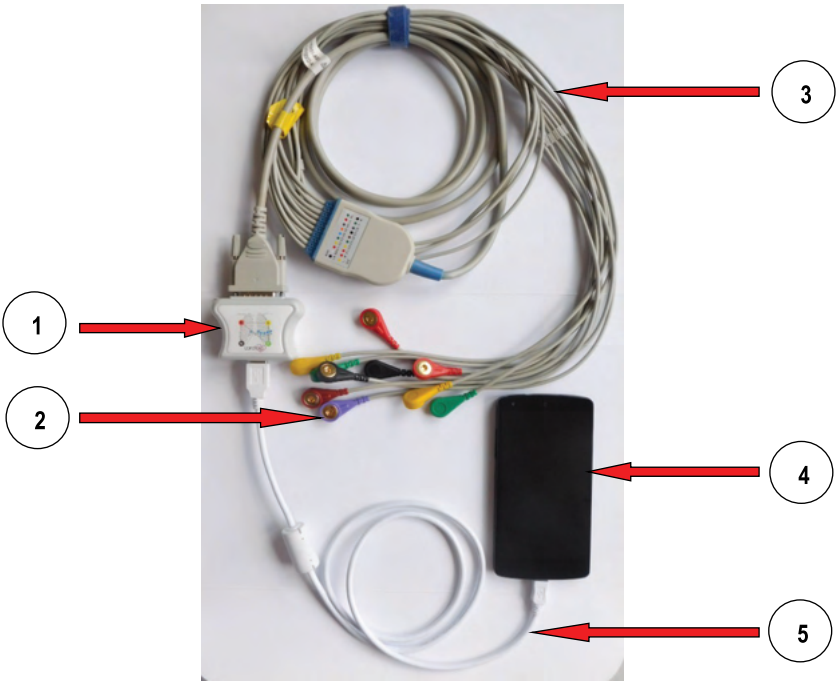
2. BASIC INFORMATION ABOUT THE MOBILE ECG DEVICE "CARDIONS E2"

Name: Mobile ECG device
Brand: CardioNS
Type: E2
Manufacturer: Panonit d.o.o. Novi Sad, Serbia
Application: For acquisition, display, interpretation, streaming and printing ECG signals
Voltage: 5V/3.3V
Power consumption: 0.5w
Number of channels: 12 (twelve)
Sampling frequency: 100 Hz – 1.066 Hz
Input signal range: ±5 mV
AD convertor resolution: 24 bits
Dimensions (without connected cables): 50 mm x 64.3 mm x 22 mm
Weight: 50 grams
Lifetime of the product: 10 years
Custom made device: NO YES Purchaser: _____
Product intented only for clinical trials: NO YES

3. DESCRIPTION OF THE MOBILE ECG DEVICE "CARDIONS E2":

Mobile ECG device CardioNS E2 (Picture 1) consists of the following parts:

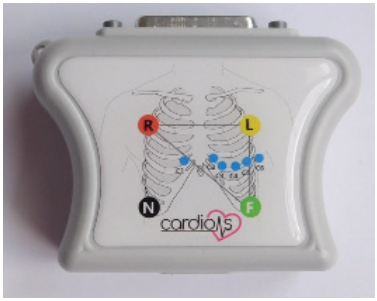
1. Plastic housing for electronics (Picture 1, position 1 and Pictures 2 and 3),
2. Electronics (Picture 3, position 3),
3. ECG leads – 10 (ten) leads (Picture 1, position 2 and Pictures 4, 4a and 4b),
4. Cables for ECG leads – 10 (ten) cables (Picture 1, position 3 and Picture 3, position 4), maximum length 2m
5. ECG pads/electrodes – 10 pieces (Picture 6 and Pictures 6a, 6b and 6c) – Not supplied with the device, patient/user buys them at pharmacies/suppliers and places them by himself
6. Mobile phone or tablet (Picture 1, position 4 and Picture 7 position 1),
7. USB cable for mobile phone or tablet (Picture 1, position 5 and Picture 3, position 5), maximum length 1m



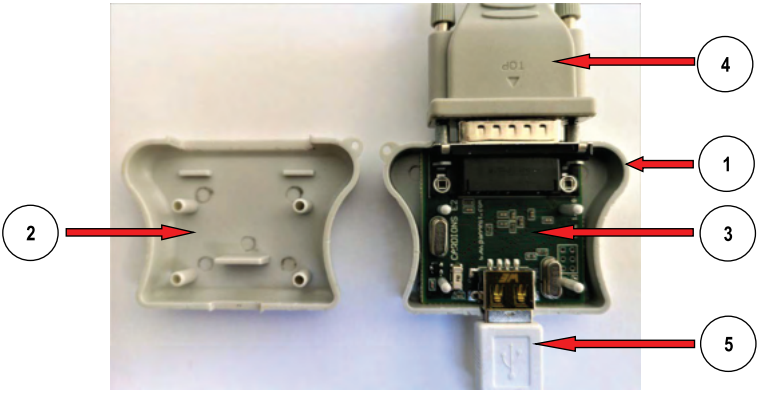
Picture 1. Cardions E2 device with mobile phone

1. Plastic housing for electronics

Plastic housing for electronics (Picture 1, position 1 and Pictures 2 and 3) is intended for installation of electronics (Picture 3, position 3). It is made from special plastic material that is safe for human use. Inside the box is electronics (Picture 3, position 3) that is used for measuring ECG signals that are sent to the mobile phone or tablet (Picture 1, position 4 and Picture 7 position 1). Plastic housing has two parts: housing body (Picture 3, position 1) and housing cover (Picture 3, position 2). On one side of the housing is the USB cable for the mobile phone or tablet (Picture 1, position 5 and Picture 3, position 5), while the other side of the housing has the cables for ECG leads - 10 (ten) cables (Picture 1, position 3 and Picture 3, position 4).



Picture 2. Plastic housing for electronics (front view)

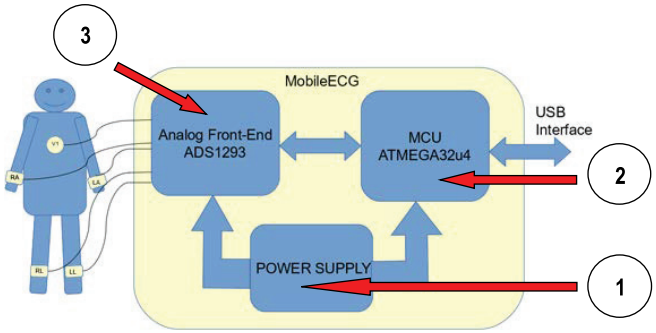


Picture 3. Plastic housing for electronics (inside view)

2. Electronics:

Electronics (Picture 3, position 3) consists of a printed circuit board with components that can acquire ECG signals from the human/patient body surface. The signal is amplified and sent to the mobile phone or tablet (Picture 1, position 4 and Picture 7 position 1) via USB cable (Picture 1, position 5 and Picture 3, position 5). Electronics is divided into three parts as it is shown in block diagram (Picture 3a). The first part is the power supply (Picture 3a, position 1). The power supply provides the 3.3V voltage for electronic components. On the input of the power supply is 5V voltage from the USB cable (Picture 1, position 5 and Picture 3, position 5). The second part consists of integrated circuit ADS 1293 (Picture 3a, position 3). This integrated circuit amplifies and partially processes signals acquired from ten ECG leads (Picture 1, position 3 and Picture 3, position 4). From signal's input, to its output, the signal passes through several processes. In the first process, the input signals are amplified. Input signals have small amplitudes, so it is necessary to amplify them in order to use them further. The next process is signal digitalization. Signals are brought to the inputs of Analog-Digital convertor, where the digitalization process takes place. After digitalization, signals pass through another process - digital filters. Digital filters are used to clean signals from noise. Afterwards, signals are ready for processing. The third part consists of microcontroller Atmega32u4 (Picture 3a, position 2).

Microcontroller is used to control the integrated circuit ADS1293 (Picture 3a, position 3) and to send acquired signals to the mobile phone or tablet via USB cable (Picture 1, position 5 and Picture 3, position 5) using the HID (Human Interface Device) protocol.



Picture 3a. Block diagram of device's electronics

Technical specification:
Input signal range: ±5 mV
AD convertor resolution: 24 bits
Number of samples in a second: 100, 200, 400, 533, 800,1066
Filters: Baseline (High pass), Notch 50 Hz (software) and LP (hardware)
Power consumption: 0.5W

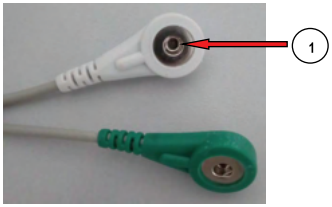
3. ECG leads:

ECG leads – 10 (ten) pieces (Picture 1, position 2 and Pictures 4, 4a and 4b) are used to connect the device with the electrodes/pads (Picture 6 and Pictures 6a, 6b and 6c) that are placed on a human/patient body.
ECG leads are connected with ten cables for ECG leads (Picture 1, position 3 and Picture 3, position 4), and ten electrodes/pads (Picture 6 and Pictures 6a, 6b and 6c) are connected with ECG leads.

ECG leads are marked with different colors and different labels:
a) European labels:
- red color – label R
- yellow color – label L
- green color – label F
- black color – label N
- white color – labels C1 to C6

b) American labels:
- white color – label RA
- green color – label RL
- black color – label LA
- red color – label LL
- brown color – labels V1 to V6

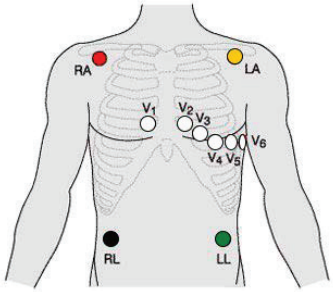
For every ECG lead there is a defined label and color, as well as where that lead is connected with ten electrodes/pads (Picture 6 and Pictures 6a, 6b and 6c) and positioned on a human/patient body. The positioning of ECG leads with 10 electrodes/pads (Picture 6 and Pictures 6a, 6b and 6c) is described in:
a) European standard - as shown in Picture 5 and Table 1,
b) American standard – as shown in Picture 5a and Table 1.



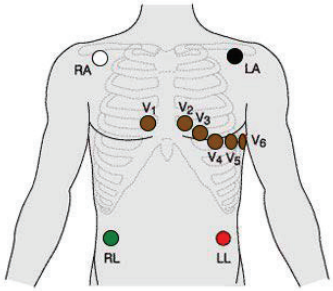
Picture 4. ECG leads

Picture 4a. ECG leads – European colors and labels

Picture 4b. ECG leads - American colors and labels



Picture 5. Positioning ECG leads with electrodes/pads on a human/patient body by European standard (IEC International Electrotechnical Commission)



Picture 5a. Positioning ECG leads with electrodes/pads on a human/patient body by American standard (AHA - American Heart Association)

Placing ECG probes with electrodes on the human body				
European standard for marking		Place of installation of ECG probes with electrodes on the human body	US standard for marking	
Color	Mark		Color	Mark
Red	R	Right shoulder or right hand	White	RA
Yellow	L	Left shoulder or left arm	Black	LA
Green	F	Left foot or upper left quadrant of the abdomen	Red	LL
Black	N	Right leg or top right quadrant of the abdomen	Green	RL
Red White	C1	Chest: 1 – the fourth interracial space on the right edge of the chest bones	Red Brown	V1
Yellow White	C2	2 – the fourth interracial space along the left edge of the chest bones	Yellow Brown	V2
Green White	C3	3 – between 2 and 4	Green Brown	V3
Brown White	C4	4 – the fifth intervertebral space in the mediocostic line	Blue Brown	V4
Black White	C5	5 – front axillary line in the same horizontal level as 4	Orange Brown	V5
Purple White	C6	6 – the mid-axillary line at the same horizontal level like 4 and 5	Purple Brown	V6

Table 1. European and American standards for labeling and positioning ECG leads with electrodes/pads on a human/patient body

4. Cables for ECG leads:

Cables for ECG leads – 10 (ten) pieces (Picture 1, position 3 and Picture 3, position 4) are used to transfer the ECG signal from ECG leads - 10 pieces to electronic circuit board (Picture 3, position 3). They also have a purpose to protect ECG signals from electrical noise.

5. ECG pads/electrodes:

ECG pads/electrodes – 10 pieces (Picture 6 and Pictures 6a, 6b and 6c) **– Not delivered with the device. The user/patient buys them at pharmacies or suppliers. They are positioned by the user/patient –** used to provide a good contact between ECG leads and skin surface of a human/patient. Better contact means less noise and the ECG signal will be better for further processing.

There are different types of pads/electrodes that can be used with CardioNS E2:

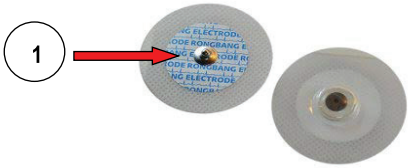
- Gel pads (Picture 6 and Picture 6a),
- Vacuum electrodes (Picture 6b),
- Electrodes as clamps for arms and legs (Picture 6c).

ECG pad/electrodes are placed on ECG leads - 10 pieces (Picture 1, position 2 and Pictures 4, 4a and 4b) by placing the connectors (Picture 6, position 1, Picture 6b, position 1 and Picture 6c, position 1) in the ECG leads openings (Picture 4, position 1).

ECG electrodes should be designed and stringently tested according to meet ANSI/AAMI EC12 on disposable ECG electrodes, ISO 10993 on biocompatibility and the European Medical Device Directive.

Some of those can be found on the following websites:

1. https://www.leonhardlang.com/ecg-electrodes
2. https://bio-medical.com/covidien-kendall-disposable-surface-emg-ecg-ekg-electrodes-1-3-8-35mm-50pkg.html



Picture 6. Gel pad – view from both sides

Picture 6a. Gel pads

Picture 6b. Vacuum electrodes

Picture 6c. Electrodes as clamps for arms and legs

6. Mobile phone or tablet:

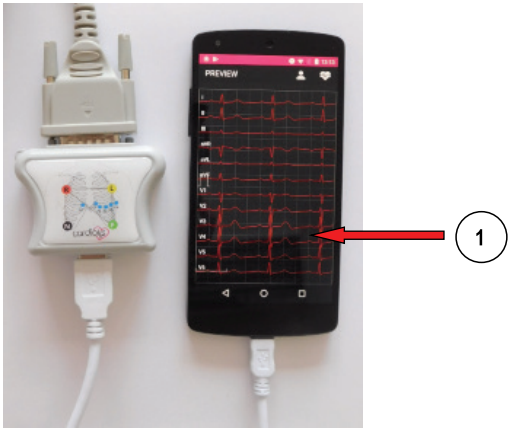
Mobile phone or tablet (Picture 1, position 4 and Picture 7, position 1) is used for displaying, processing and interpretation of a signal acquired from the device. Only mobile phones and tablets that have OTG (On-The-Go) function and CE mark can be used.

Minimum phone or tablet requirements:
CPU Speed: Octa-core 1.95Hz
RAM: 6 GB
Recommended free space: 200 MB
USB: USB Type-C
OS: Android 7.0 (Nougat)

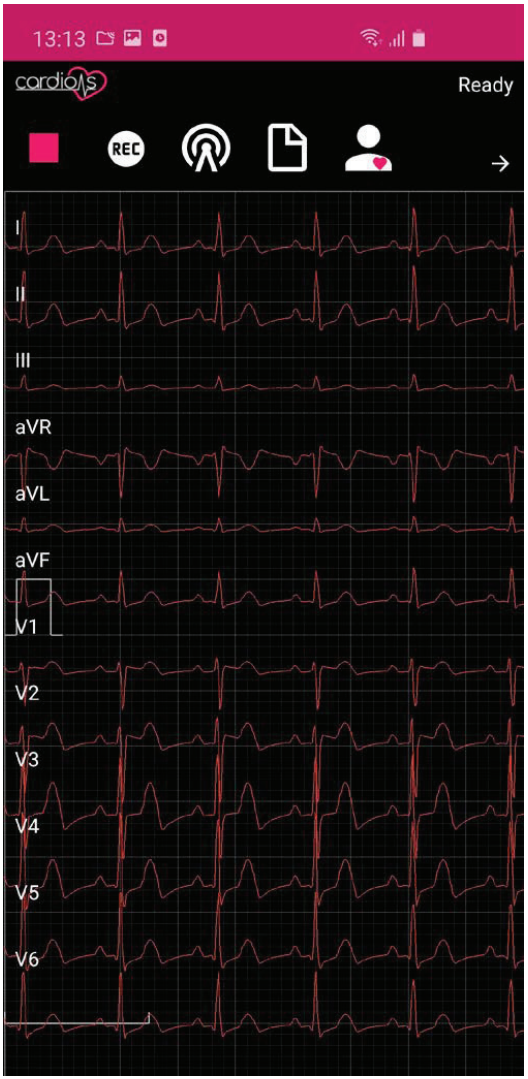
Mobile phone or tablet is connected with the device via cable (Picture 1, position 5 and Picture 3, position 5). Mobile phone or tablet have to have installed the application "Cardions Heart Outline" (Picture 9) (https://play.google.com/-store/apps/details?id=com.panonit.cardions) (Picture 8) that displays, processes and stores ECG signals. The application can show following signals (leads): I, II, III, aVR, aVL, aVF and precordial V1-6. Mobile phones or tablets are also used to provide power for the electronics (Picture 3, position 3) that is placed in the plastic housing for electronics (Picture 1, position 1 and Pictures 2 and 3).

7. USB cable for mobile phone or tablet:

USB cable for mobile phone or tablet (Picture 1, position 5 and Picture 3, position 5) is used to connect the device with mobile phone or tablet (Picture 1, position 4 and Picture 7, position 1).



Picture 7. Mobile phone or tablet - displaying ECG signal



Picture 8. Application “Cardions Heart Outline”

4. DESCRIPTION OF THE MOBILE ECG DEVICE "CARDIONS E2" FUNCTIONING:

Device "CardioNS E2" (Picture 1) is connected with a mobile phone or tablet (Picture 1, position 4 and Picture 7, position 1) via USB cable (Picture 1, position 5 and Picture 3, position 5). USB cable has two functions: one is to give power to the device, and the other is to transfer data between the device and mobile phone or tablet. After connecting the device with mobile phone or tablet, the device is powered and mobile phone or tablet register the device. In case it is recognized, parameters defined in the application are sent to the device. Microcontroller (Picture 3a, position 2), which is located on the printed circuit board, accepts the parameters, process them and adjusts the ADS1293 (Picture 3a, position 3). Communication between microcontroller and ADS1293 is performed through SPI (Serial Peripheral Interface) protocol. After this, the device is ready to acquire ECG signals. ECG signals have very small amplitudes and they are acquired through pads or electrodes. Signals are transferred through cables. When ECG signals arrive to the ADS1293, they are amplified 3.5 times. Afterwards, the next step is analog to digital conversion. Digital signals pass through filters, which reduce the noise. Processed signals are stored in input registers of the ADS1293. ADS1293 notifies the microcontroller that signals are ready for reading. Microcontroller reads input registers and transfers data to a certain location in microcontroller's memory. Data is transferred with SPI protocol. Depending on the adjusted number of samples per second, readings are performed every: 1 ms, 1.25 ms, 1.85 ms, 2.5 ms, 5 ms and 10 ms. After 6 reading cycles, microcontroller sends data to the mobile phone or tablet via USB cable using HID (Human Interface Device) protocol. When the data is sent, microcontroller empties its memory location and starts the next cycle of reading data. When data arrives to the mobile phone or tablet, processing takes place. Data is passed through high frequency filters, and if it is necessary, data is passed through another filter which eliminates 50 Hz signals that originate from power network radiation. At the end, the signal is displayed on the screen of a mobile phone or tablet. If recording option is selected, data is saved to the mobile phone or tablet's memory.

5. DESCRIPTION OF THE INTENDED USE OF THE MOBILE ECG DEVICE "CARDIONS E2":

Mobile ECG device **"CardioNS E2"** is intended for: acquisition, display, interpretation, streaming and printing ECG signals.
Mobile ECG device "CardioNS E2" cannot be used for other purposes.
It can be used at homes or in clinics and hospitals, both by medical experts and by the general population.
Medical product „CardioNS E2" can be used without age restrictions.

6. WARNING ABOUT THE WAYS HOW MOBILE ECG DEVICE "CARDIONS E2" CANNOT BE USED:

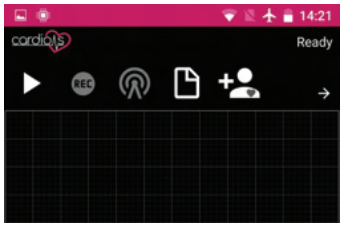
Mobile ECG device "Cardions E2" cannot be used:
1. In other purposes than described in Section 5 of this user manual
2. In combination with mobile phone and/or tablets which do not support OTG function and which do not have CE mark
3. With cables or adapters not supplied or approved by the manufacturer.

7. INSTRUCTION FOR CONNECTING THE MOBILE ECG DEVICE "CARDIONS E2"

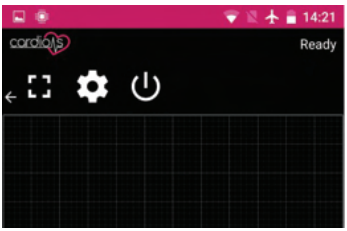
Device "CardioNS E2" (Picture 1) is connected with mobile phone or tablet (Picture 1, position 4 and Picture 7, position 1) via provided USB cable (Picture 1, position 5 and Picture 3, position 5).

8.INSTRUCTION FOR OPERATING AND USING THE MOBILE ECG DEVICE "CARDIONS E2"

Before using the device, it is necessary to place the electrodes/pads on appropriate positions on a patient's body (Picture 5 and 5a and Table 1). Firstly, the device is connected with a mobile phone or tablet. After connecting the device, the next step is to start the application "Cardions Heart Outline" (Picture 9). In the upper right corner of the screen status "Ready" is displayed, and below the message, application icons are displayed meaning that the device is ready for usage.



Picture 9.a Application "Cardions Heart Outline"



Picture 9.b Application "Cardions Heart Outline"

"Play" icon

"Record" icon

"Streaming" icon

"Open record" icon

"Patient" icon

"Extend" icon

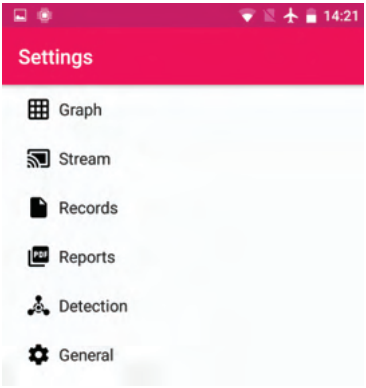
"Settings" icon

"Exit" icon

Icon **"Play"** is used to start and stop displaying signals on the screen.
Icon **"Record"** starts and stops recording signals.
Icon **"Streaming"** starts and stops streaming data in a network.
Icon **"Open record"** opens the menu related with previously saved signals.
Icon **"Patient"** is used for adding and updating patient info.
Icon **"Extend"** is used for full-screen application mode.
Icon **"Settings"** is used for various settings of the application.
Icon **"Exit"** is used to close and exit the application.

If the device is not connected, icon **"Play"** will not be available, while icons **"Record"** and **"Streaming"** requires starting signal acquisition. When signal acquisition start, icons **"Open record"**, **"Patient"** and **"Settings"** become inaccessible.

When entering the settings, using icon **"Settings"**, menu with 6 (six) submenus opens like on Picture 10.



Picture 10. Contents of the "Settings" menu

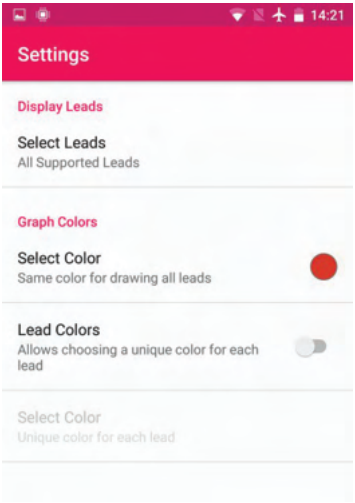
Settings menu content:

1. **"Graph"** is used to set how the signals are going to be displayed on the screen;
2. **"Stream"** is used for streaming configuration;
3. **"Records"** is used for options about recording the signal;
4. **"Reports"** is used to set up options related to generating reports;
5. **"Detection"** is used to turn on and off pulse sound signalization ("QRS");
6. **"General"** has general settings for the application.

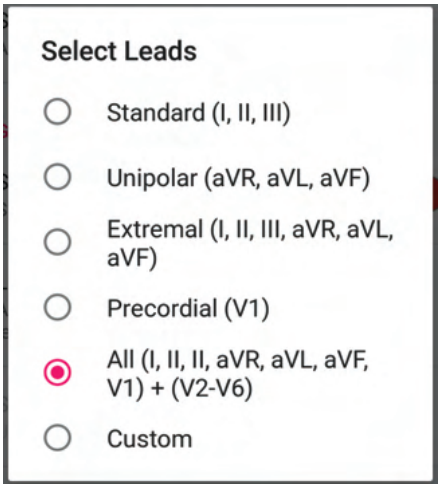
1. Submenu „Graph"

Submenu **"Graph"** (Picture 11) has the following options to adjust the graph:
1.1 Option **"Select Leads"** is used to select which leads (signals) will be shown on the screen.
Options for choosing (Picture 12):
1.1.1 Standard (bipolar) leads (I, II i III),
1.1.2 Unipolar leads (aVR, aVL, aVR),
1.1.3 Bipolar + unipolar,
1.1.4 Precordial leads (V1),
1.1.5 All,
1.1.6 User defined leads to display.

1.2 Option **"Graph Color"** (Picture 11) opens the color palette:
1.2.1 **"Select Color"** enables to choose one color for all leads
1.2.2 **"Lead Colors"** enables to choose a color separately for each lead



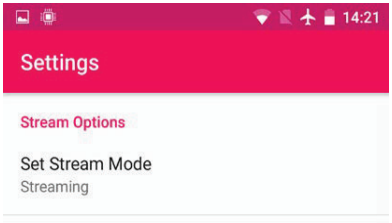
Picture 11. Submenu "Graph"



Picture 12. "Select Leads" option

2. Submenu "Stream"

Submenu **"Stream"** (Picture 13) contains following options:
2.1 Option **"Set Stream Mode"** allows switching stream mode (**"Streaming"** or **"Monitoring"**) in wireless data transmition. Option **"Monitoring"** allows to watch signals from another device via network. Option **"Streaming"** allows that you can start server mode on your mobile device or tablet and stream data to other devices.

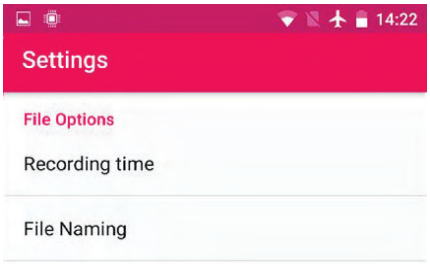


Picture 13. Submenu "Stream"

3. Submenu "Records"

Submenu **"Records"** (Picture 14) contains following options:
3.1 With option **"Recording time"** we set how long the recording will last. If, for example, we select 30 seconds, at the start of the recording time will appear in the upper right corner which will count to zero. When time expires, the recording stops automatically.
3.2 Option **"File Naming"** serves to select a convention for file naming that contains information about the record. We can choose one of the following conventions:

3.2.1 By the name of the patient,
3.2.2 By time when file is recorded,
3.2.3 By combination of the above.



Picture 14. Submenu "Records"

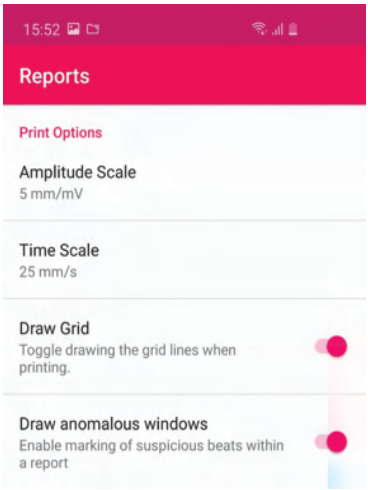
4. Submenu "Reports"

Submenu **"Reports"** (Picture 15) contains following options:
4.1 In section **"Print Option"** we set resolution and size of graph on the mobile device, tablet or external printer. Several options are available:

4.1.1 **"Amplitude Scale"** sets up ECG signal amplitude when printing on a printer or millimeter paper.
Following options are available:
4.1.1.1 5 mm/mV,
4.1.1.2 10 mm/mV,
4.1.1.3 20 mm/mV,
4.1.1.4 40 mm/mV.

4.1.2 **"Time Scale"** sets up ECG time axis when printing on a printer or a millimeter paper.
Following options are available:
4.1.2.1 25 mm/s,
4.1.2.2 50 mm/s,
4.1.2.3 100 mm/s.

4.1.3 **"Draw Grid"** is used when printing is performed on empty paper sheets (without millimeter raster).
4.1.4 **"Draw anomalous windows"** is used to mark regions that are recognized as suspicious.



Picture 15. Submenu "Reports"

5. Submenu "Detection"

In submenu **"Detection"** (Picture 16) the following options are available for controlling the recognition of real-time pulse sensing, as well as options related to the detection and marking of suspected areas in the subsequent review of the recording:

5.1 Under section **"Real time"** the following options are available:

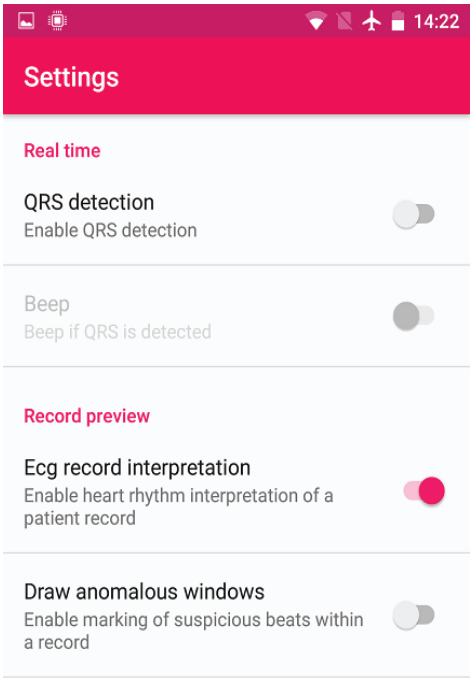
5.1.1 Option **"QRS detection"** includes and excludes detection of QRS complexes.

5.1.2 Option **"Beep"** activates and deactivates the pulse sound signal.

5.2 Under section **"Record preview"** the settings are related to the preview of the recorded signals:

5.2.1 Option **"Ecg record interpretation"** activates and deactivates the option to recognize cardiac abnormalities (Picture 16),

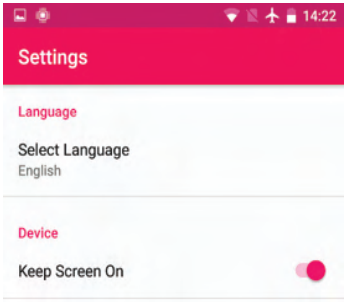
5.2.2 Option **"Draw anomalous windows"** activates and deactivates the option to mark suspicious beats in preview mode (Picture 16).



Picture 16. Submenu "Detection"

6. Submenu "General"

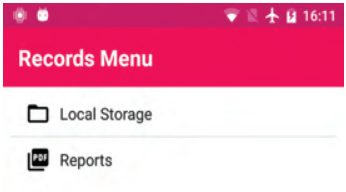
Submenu **"General"** (Picture 18) contains following options:
6.1 Option **"Select Language"** is used to change the language in the application.
6.2 Option **"Keep Screen On"** is used to keep screen on while using the applicatoin.



Picture 18. Submenu "General"

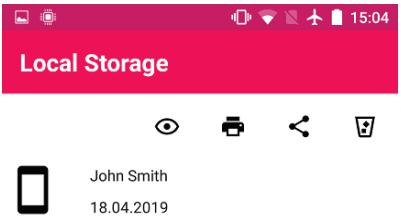
ECG signal recording and printing

ECG signal recording is performed in the following way:
After ECG device is connected, user should start acquiring ECG signal by pressing icon **"Play"**. When the signals appear on the screen, recording starts with clicking icon **"Record"** and it will last until icon **"Record"** is pressed again. Recording time is limited only with the memory storage capacity of a mobile phone or tablet. When displaying ECG signals is active, recording can be started multiple times. Every recording creates a separate file. No matter how many leads are displayed on the screen, recorded file always contains all leads. After signals are saved, it is possible to view them. Clicking the icon **"Open record"** opens a new page with the record menu (Picture 19).



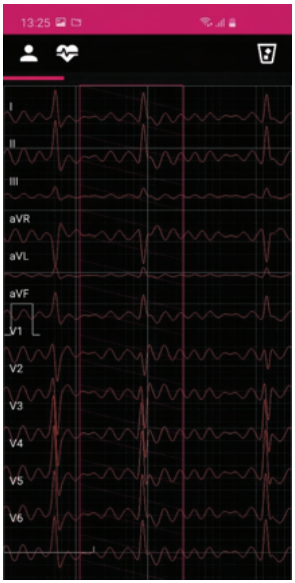
Picture 19. "Records" menu

Clicking on the submenu option **"Local Storage"** opens the new page with list of previously recorded files (Picture 20). By selecting item form list, opens the menu with preview, print (Picture 24), share and delete option.



Picture 20. List of records

Upon opening, the user can select which signals will be displayed, since during recording all leads are recorded (it does not matter which signals are chosen for display. Picture 21 displays twelve signals. Signals can be zoomed in and out.

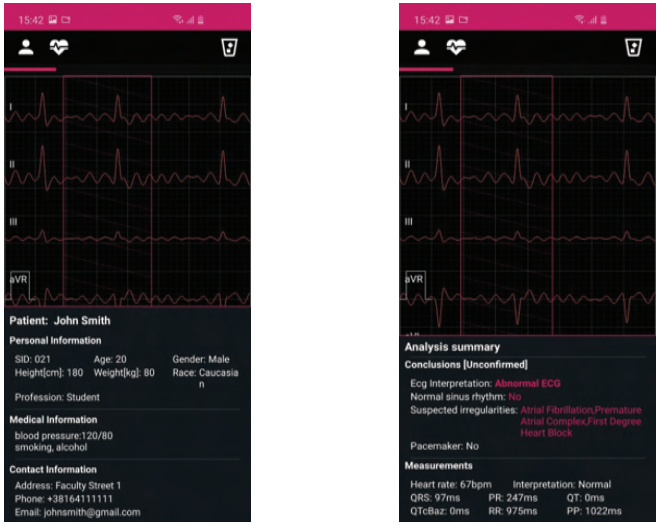


Picture 21. Record preview

While watching record, you can see all information about the patient and about the signal. Clicking on icon "**Patient**" opens a new window that contains information about the patient and his health status.

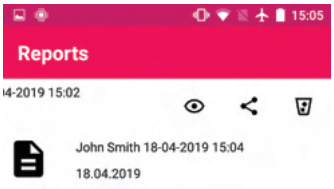
Clicking on icon "**Analyse**" opens the new window with information about potential heart anomalies.

On the top right corner, there is an icon "**Delete**" for deleting the opened record.



Picture 22. Displaying recorded signals, information about patient and about suspected irregularities

Clicking on the submenu **"Reports"** opens list with previously created reports (Picture 23). By selecting item from list, opens the menu with preview, share and delete option.



Picture 23. Reports list

Picture 24. Signals printed on a paper with millimeter raster

Adding patient

After click on icon **"Patient"** the window for adding patient opens (Picture 25). Fields "Card Number", "Name" and "Last Name" are required while the rest of the form can remain empty. When recording is done, entered patient data will be encrypted and as such stored along with signal information in the same file.

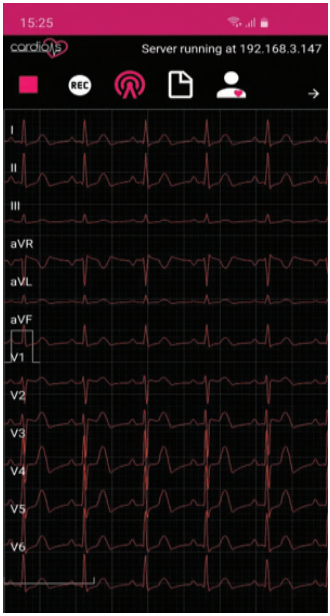
Picture 25. Form for adding patient

Streaming mode

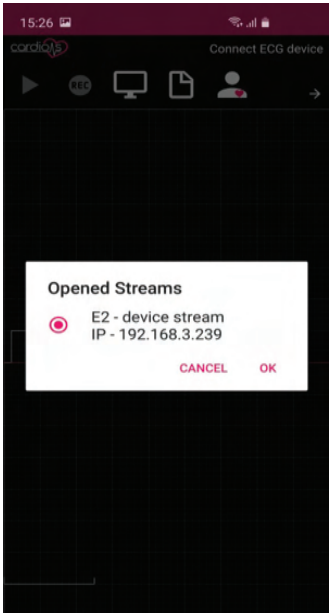
Streaming mode is described in more details in submenu 2 (submenu **"Stream"**).

When the ECG device is connected with a mobile phone or tablet, and "Streaming" mode is turned on, icon **"Stream"** appears. Clicking this icon starts a server on a mobile phone or tablet and after that, it is possible to connect other mobile phones or tablets to the server via Wi-fi connection. All connected devices can display ECG signals from the running server.
When the server is running, a message is displayed in the upper right corner of the screen stating that the server is running and displaying its IP address (Picture 26).

Mobile phones, tablets and PCs that are connected to the Wi-fi network, and “Monitoring” mode is turned on, instead of “Stream” icon, icon  “**Monitoring**” appears.
Clicking this icon opens a dialog with all running servers on mobile device or tablet (Picture 27). After choosing the stream and pressing the ok button, the connection is established and ECG signals appear on the screen.



Picture 26. “Streaming” mode



Picture 27. Form for choosing stream in “Monitoring” mode

9. TROUBLESHOOTING GUIDE

In case of changes in normal operation of mobile ECG device "CardioNS E2", following measures should be performed:

No.	Changes in normal operations	Measures to perform	Note
1.	Signals on the screen are "frozen"	Close the application and disconnect the ECG device. Connect the ECG device again and then start the application	If the problem appears again, before connecting the ECG device, restart the mobile phone or tablet.
2.	Signals have a lot of noise	Check if electrodes/pads are attached correctly Replace electrodes/pads	
3.	Signals are distorted	Check if electrodes are positioned correctly	
4.	When the application is started ECG device is not recognized	Mobile phone/tablet should be replaced with a mobile phone/tablet that supports OTG function	
5.	Recorded signals cannot be sent over Internet	Check internet connection	

In case other irregularities are experienced, contact the manufacturer ("Panonit" d.o.o., Novi Sad, Serbia) with contact details given in Section 1 of this user manual.

10. INFORMATION ABOUT THE MEASURES OF PROTECTION THAT USERS MUST TAKE

Perform the following inspections daily:

- Check for cracks or breaks on the ECG cable with leads, the USB cable, and the ECG device housing.
- Check for bent or missing pins on all cables.
- Check all cable and cord connections; reseat if any connectors are loose.

When storing the ECG module and accessories, observe the environmental storage conditions that are identified in the product specifications.

During the operation of mobile ECG device "CardioNS E2" users must take following measures of protection:

1. Prohibit access and usage of mobile ECG device "CardioNS E2" for all minors and persons disturbed in development

2. Allow access and usage of mobile ECG device "CardioNS E2" only to adults and persons which are not disturbed in development and who previously are familiar with device's user manual.

3. During operation of mobile ECG device "CardioNS E2" only mobile phones or tablets with OTG function and with CE mark can be used.

4. Modifications and/or adjustments cannot be made on mobile ECG device "CardioNS E2".

5. Repairs and part replacements can be done only by qualified persons authorized by "Panonit" d.o.o. Novi Sad, Serbia.

6. Mobile ECG device "CardioNS E2" is not delivered with electrodes/pads. Users should buy them on their own. Electrodes/padsmust be safe for human use and that is proved with corresponding laboratory analysis or certificates that the seller or distributer has to provide and hand them to the user during purchase.

7. During usage of mobile ECG device "CardioNS E2" users are advised to use single-use medical gloves.

8. Mobile ECG device "CardioNS E2" should not be used in the vicinity of heat source or electromagnetic radiation source.

11. INFORMATION ABOUT OTHER RISKS THAT OCCUR DESPITE THE MEASURES TAKEN TO ENSURE SAFE CONSTRUCTION, SAFETY PROTECTION AND THE APPLICATION OF ADDITIONAL PROTECTIVE MEASURES:

No.	Hazard (product property)	Risk level	Notes
1	Product is small and contains small parts	LOW	
2	Possibility to swallow small product part	LOW	
3	Low voltage (DC 220 V)	LOW	
4	Low intensity of electromagnetic field radiation; Low or high frequency (microwaves);	LOW	
5	Microbiological contamination	LOW	
6	User does not recognize warning signs and/or does not understand symbols	LOW	

12. DESCRIPTION OF THE MOBILE ECG DEVICE "CARDIONS E2" PACKAGING

Mobile ECG device "CardioNS E2" is delivered in the following packaging:

No.	Package name	Package description	Number of devices in the packaging	Package contents	Notes
1	Box	Cardboard box for 1 (one) device (product)	1	1. Device "CardioNS E2" 2. USB OTG cabel 3. Cabel with leads 4. User manual 5. Declaration of conformity	

13. DESCRIPTION OF PREVENTIVE MAINTENANCE FOR MOBILE ECG DEVICE "CARDIONS E2"

For mobile ECG device "Cardions E2" following measures of preventive maintenance should be taken:

13.1 Updating the software for mobile ECG device "Cardions E2"
The first, and every other periodic software update can be downloaded from the following link:

https://play.google.com/store/apps/details?id=com.panonit.cardions.

After downloading the software, it is necessary to install it on a mobile phone or tablet that will be used with mobile ECG device "CardioNS E2".

Users are advised to perform periodic software update once in every 3 (three) months, because the manufacturer can modify the software in some parts or in whole.

14. SPECIFICATION OF EQUIPMENT THAT IS NOT DELIVERED WITH MOBILE ECG DEVICE "CARDIONS E2"

Mobile ECG device "CardioNS E2" is not delivered with electrodes/pads (Picture 6 and Pictures 6a, 6b and 6c). Users should buy them on their own. Electrodes/pads must be safe for human use and that is proved with corresponding laboratory analysis or certificates that the seller or distributer has to provide and hand them to the user during purchase.
Mobile ECG device "CardioNS E2" is not delivered with mobile phone or tablet. User should provide a mobile phone or tablet with OTG support and with CE mark.

15. DATA ON THE RADIATION LEVEL OF MOBILE ECG DEVICE "CARDIONS E2"

Radiation level emitted by the mobile ECG device "CardioNS E2" is within allowed limits, which is confirmed by the accredited laboratory.
EMC (electromagnetic compatibility) examination is performed according to:
1. EN 55011:2011
2. EN 55011:2011/ A1:2011
3. EN 55011:2017

Incorrect device usage does not increase radiation level.

Test emissions	Conformity	Electromagnetic surrounding
RF emissions CISPR 11	Group 1	The above listed models use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The above listed models are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

16. INFORMATION ON STERILIZATION:

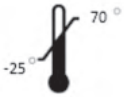
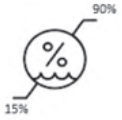
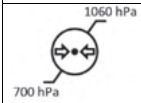
Sterilization and re-sterilization of mobile ECG device "CardioNS E2" does not have to be performed.

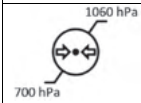
17. INFORMATION ON MOBILE ECG DEVICE "CARDIONS E2" ACCURACY

Accuracy of measured parameters is in the following boundaries:
1. Voltage - 95 %
2. Time - 97.5 %
3. Number of heart beats - 97 %
4. A uniform sampling of the ECG signals was employed, the ECG signals were sampled with at least 500 samples/s per channel during data acquisition
5. The skew between channels was not larger than 100 μs
6. Amplitude quantisation was ≤ 5 μV/LSB referred to input (μV/LSB)
7. A non-uniform sampling rate of equivalent performance was demonstrated and the sampling rate was at least 500 samples/s per channel within QRS complexes

18. PRODUCT LABEL DESCRIPTION

<table>
<tr><th>Symbol</th><th>Name</th><th>Standard / Note</th></tr>
<tr><td>  </td><td>Medical device manufacturer
Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.</td><td>ISO 15223-1</td></tr>
<tr><td>  </td><td>Company logo</td><td>None</td></tr>
<tr><td>  </td><td>Serial number
Indicates the manufacturer's serial number so that a specific medical device can be identified.</td><td>ISO 15223-1</td></tr>
<tr><td>  </td><td>Catalogue number</td><td>ISO 15223-1</td></tr>
<tr><td>  </td><td>Date of manufacture
Indicates the date when the medical device was manufactured.</td><td>ISO 15223-1</td></tr>
<tr><td>  </td><td>Type CF applied part</td><td>IEC 60417-5336</td></tr>
<tr><td>  </td><td>Batch code
Indicates the manufacturer's batch code so that the batch or lot can be identified.</td><td>ISO 15223-1</td></tr>
<tr><td>IP22</td><td>Water ingress protection rating 22.
Digits explanation
<table>
<tr><td>First digit (solids)</td><td>2</td><td>Effective against fingers or similar objects (>12.5mm)</td></tr>
<tr><td>Second digit (liquids)</td><td>2</td><td>Vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position</td></tr>
</table></td><td>IEC 60529</td></tr>
<tr><td>  </td><td colspan="2">Authorized representative in the European Community
Indicates the Authorized representative in the European Community.</td><td>ISO 15223-1</td></tr>
</table>

	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1
CE 1304	CE marked product with NB number	Medical Device Directive 93/42/EEC, as amended with 2007/47/EEC
	The WEEE symbol, indicating separate collection for WEEE- Waste of electrical and electronic equipment, consists of the crossed-out wheeled bin, as shown below. The symbol must be printed visibly, legibly and indelibly. The symbol is required per the Article 11(2) of the WEEE Directive.	WEEE Directive
RoHS2	Symbol related to restriction of the use of certain hazardous substances in electrical and electronic equipment.	Directive 2011/65/EU, COMMISSION DELEGATED DIRECTIVE (EU) 2015/863, Directive (EU) 2017/2102
	Follow instructions for use	IEC 60601-1
	Temperature limit for storage and transport conditions.	ISO 15223-1
	Humidity limitation for storage and transport conditions.	ISO 15223-1
	Atmospheric pressure limitation for storage and transport conditions.	ISO 15223-1
	Temperature limit for operating conditions.	ISO 15223-1

	Humidity limitation for operating conditions.	ISO 15223-1
	Atmospheric pressure limitation for operating conditions.	ISO 15223-1

19. STORAGE AND USAGE CONDITIONS

Storage and transport environmental conditions
1. Temperature: -25°C to +70°C
2. Relative humidity: 15% to 90% (limited condensation)
3. Atmospheric pressure: 700 to 1060 hPa

Operating environmental conditions:
1. Temperature: 5°C to +40°C
2. Relative humidity: 15% to 90% (limited condensation)
3. Atmospheric pressure: 700 to 1060 hPa

20. CLEANING AND MAINTENANCE

1. Clean the device with a cloth dampened with water or mild detergent, then wipe it with a dry cloth after each use.
2. Sterile pads/electrodes intended for single use discard after use and use new ones.
3. Pads/electrodes intended for multiple usage, clean wipe using a cloth dampened with disinfectant alcohol.
4. Do not wipe the device with benzene, gasoline, paint thinner, concentrated alcohol or other volatile detergents.
5. Do not disassemble the product. There are no user serviceable parts. Repairs should only be carried out by Panonit authorized personnel.
6. For every patient/user use new ECG pads/electrodes.

21. CONTRAINDICATIONS

Some patients/users may have allergies or, more commonly, sensitivity to the electrodes adhesive. In these cases, hypoallergenic alternatives are available from various manufacturers.

22. PRECAUTIONS AND WARNINGS

Following precautions and security measures are advised:
1. Mobile ECG device "CardioNS E2" must not be used during an MRI scan
2. The ECG device "CardioNS E2" should not be used on patients who are linked to heart lung machines.
3. Device must not be used on patients with sensitive skin or allergies
4. If electrodes/pads are applied on places with too much body fat, body hair or very dry skin, a successful reading may not be possible
5. Static electricity should be avoided

6. Do not expose to strong electromagnetic fields.
7. Do not store in extremely hot, cold, humid, wet, or bright conditions.
8. Do not take a recording while driving.
9. Do not use "CardioNS E2" while charging your phone.
10. Do not take a recording if the electrodes are dirty. Clean them first.
11. Keep components out of reach of children.
12. "CardioNS E2" makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the products as instructed. Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional for clinical decision making.
13. Do not use in combination with mobile phone and/or tablets which do not support OTG function and which do not have CE mark
14. Do not drop or bump with excessive force.
15. Do not continue to use until further instructed by a physician if your skin is irritated or inflamed around the electrodes
16. Do not use to diagnose heart related conditions.
17. Always disperse any static electricity from patient's body before handling the device
18. ⚠ WARNING: Do not put the device into mouth in any circumstances!
19. ⚠ WARNING: Possibility of strangulation due to cables, particularly due to excessive length! Use device exactly as described in user manual!
20. ⚠ WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
21. ⚠ WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
22. ⚠ WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
23. ⚠ WARNING: Do not allow the conductive parts of the electrodes, or associated connections of defibrillation-proof applied parts, including the neutral conductor of the electrodes, to come into contact with other conductive parts, including earth ground. Otherwise, an electrical short might result, risking electric shock to patients and damage to the device.
24. ⚠ WARNING: To provide protection against the effect of the discharge of a cardiac defibrillator and against high-frequency burns use only cables and accessories provided with the device. The use of any other accessories can result in inaccurate patient data, can damage the equipment, and can void your product warranty.
25. ⚠ WARNING: To avoid serious injury or death, take precautions consistent with good clinical practice during patient defibrillation:
    a. Avoid contact with the electrocardiograph, patient cable, and patient.
    b. Place defibrillator paddles properly in relation to electrodes..
26. ⚠ WARNING: To avoid serious injury or death, take precautions consistent with good clinical practice during patient defibrillation:
    a. Before defibrillation, verify that patient leads are properly connected to the the ECG module. Loose ECG leads can divert defibrillator current.

b. After defibrillation, check cables and inspect the pins for charring (black carbon marks).

27. ⚠ WARNING: For patients with a pacemaker, maintain a minimum of 15 cm between the device and pacemaker. Power down the ECG module immediately and provide appropriate patient care if you suspect the ECG module has affected the pacemaker.

28. ⚠ WARNING: This device is not designed for direct cardiac application.

29. ⚠ WARNING: If an electrosurgical unit is used, place the ECG cables as far as possible from the site of the surgery and from the electrosurgical cables. This will minimize interference and the risk of burns to the patient. Ensure that the electrosurgical return cable (neutral) is well attached and making good contact with the patient.

30. ⚠ WARNING: Electrode connector of a lead wire shall, when separated from the electrode, have an air clearance between connector pins and a flat surface of at least 0.5 mm.

APPENDIX I
GENERAL KNOWLEDGE ABOUT ECG AND SOFTWARE PERTURBATION PREVENTION PROTOCOL

Read the following potential conditions in order to avoid potential mistakes that might be caused by software perturbation. If unusual (abnormal) recording occur, check if all electrodes were positioned correctly and repeat recording (the software automatically detects if electrode is disconnected and notifies the user). In case of abnormal ECG waveforms (as described below in section b)) occur in repeated recording, please go to the hospital.

If ECG application continuously crashes, contact manufacturer's technical support. (This might happen in case user installed custom Android operating system).

a) **Normal sinus rhythm:** In sinus conditions, SA node paces the heart with the regularly rate and the normal rhythm. The heart rate is in the range of 60 to 100 times per minute and the rhythm is regular. P wave is normal and each one is followed by a QRS wave. P-R interval: 0.12~0.20s; QRS wave: 0.06~0.10s; No ectopic ECG activity.
Symptom: Sinus rhythm, heart rate: 60~100bpm
Indication: Normal

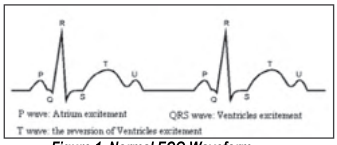


Figure 1. Normal ECG Waveform

b) **Several abnormal ECG waveforms**
Tachycardia: The heartbeat becomes faster. Tachycardia is determined by the rhythm of the heart, the average rhythm beats faster than 100 times a minute is considered as Tachycardia. The result description "Suspected fast beat" in this device may be doubted as Tachycardia.
Symptom: heart rate>100bpm
Indication: It may occur with the normal people who have these physiology conditions: rage, fatigue, smoking, drinking too much alcohol, excessive coffee and strong tea, etc.
Pathology: anemia, Hyperthyroidism, blood hypoxia, myocarditis, hypokalemia, fever, influence of some medication (such as atropine, epinephrine etc.).
Suggestion: If it belongs to pathology condition, please go to the hospital.


Figure 2. Tachycardia Waveform

Bradycardia: The heartbeat becomes more slowly. It is determined by the rhythm of the heart, the average rhythm is less than 60 beats per minute is considered as Bradycardia. The result description "Suspected slow beat" in this device may be doubted as Bradycardia

Symptom: heart rate<60bpm
Indication: It occurs when healthy people fall asleep, and it can be found in athlete (or those who love doing sports frequently), old people, or vagus excitement person.
Pathology: Sick sinus syndrome, Ischemic heart disease, Cardiomyopathy, intracranial hypertension, increased hypokalemia,Low temperature, period of convalescence of acute infectious disease or after use some medicines such as digitalis. **Suggestion**: If it belongs to the pathology condition, please see the doctor.

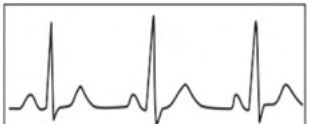


Figure 3. Bradycardia Waveform

Premature beat: In a normal beat a QRS waveform appears prematurely and is followed by a comeback pause. The result description "Suspected occasional short beat interval" in this device may be doubted as Premature beat. What is premature beats ? It is premature contraction. The normal heart beat is always regularly, and each beat interval is also symmetrically; Premature beat is out of this general regulation, the heart beats prematurely and followed by a long time interval; the phenomena of a premature beat between two heart beats is

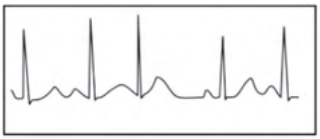


Figure 4. Premature beat

called inserting premature beat. The display of "early beat" may be suspected Premature beat. According to different original positions, it can be divided into Premature aerial Contraction, Premature Nodal Contraction and Premature Ventricular Contraction (PVC), which needed to be judged by experts.

Symptom: The heart beat is arrhythmic, it occurs as the phenomenon that the heart suddenly beats and then stops for a while. Some people have palpitation or have no symptom.

Indication: The premature beat can be found occasionally in healthy people, with no distinct symptom or sometimes with palpitation. This may be caused by fatigue, anxiety, insomnia, smoking too much, or drinking too much wine, coffee, strong tea etc. It can be recovered without treatment. However, if premature beat occurs frequently, continuously or in multi-focus, it will indicate functional cardiovascular disease. Please see a doctor as soon as possible.

Suggestion: The character of premature beat needs professional to confirm, so please save the temporal figure in time. When seeing a doctor , you can recall it to doctor to judge the character of premature （Premature atrial Contraction, Premature Nodal Contraction, Premature Ventricular Contraction or multi-focus premature beat） and help cure.

Testee's Symptom: Normal heart beat is followed by a premature beat.

Bigeminy: It is a type of PVC in which a normal beat is coupled with a premature beat. Because of its trigger cardiac abnormal pacemaker in different position, it divided into arial, ventricular and node. In the clinic medically, the ventricular is the most common, aria is more common, but the node is rarely found.

Indication: PVC occurs frequently.

Suggestion: Please see the doctor

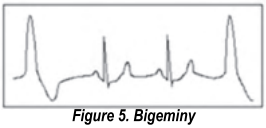


Figure 5. Bigeminy

Trigeminy: It is a type of PVC in which two normal beats are coupled with a premature beat. Because of its trigger cardiac abnormal pacemaker in different position, it divided into Arial, ventricular and node. If ventricular trigeminy occurs 3 times continuously, please see a doctor as soon as possible.

Indication: PVC occurs frequently.

Suggestion: Please see the doctor.

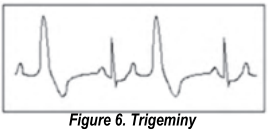


Figure 6. Trigeminy

Short run of tachycardia: PVC (Premature Ventricular Contraction) occurs more than 3 times continuously.

Testee's Symptom: PVC occurs more than 3 times continuously. The heart beat is fast and regularly, but starts and stops suddenly. According to the different of active original position, it can be divided into: Paroxysmal ventricular tachycardia, Paroxysmal supraventricular tachycardia
(Needing professional to judge).

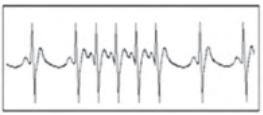


Figure 7. Tachycardia

1) Paroxysmal supraventricular tachycardia：By atrial and nodal extrasystole cause to happen, frequency >180bpm （time/minute） .

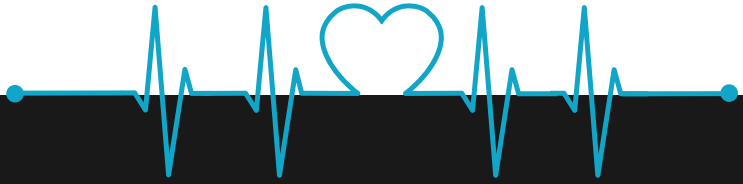
Indication：Most commonly found in healthy people, it causes by deep respiration, tachypnea, positional changes, swallow, rage etc. It also appears in functional cardiac disease, such as Wolff - Parkinson-White Syndrome, rheumatic heart disease, coronary heart disease, Cardiomyopathy, Congenital heart disease, medicinal reaction （digitalis toxicosis） etc.

Suggestion：If it occurs time after time, please see the doctor as soon as possible.

2) Paroxysmal ventricular tachycardia：Caused by Premature Ventricular Contraction, Heart Rate >140bpm. **Indication**：Most commonly found in heart disease patient, it can cause ventricle fibrillation if it's serious, so the tester needs to see a doctor immediately.

Suggestion：The character of short run needs professional to confirm, so please save the temporal figure in time. And you can provide it to doctor as a reference.

PanonIT



PANONIT D.O.O.
MIROSLAVA ANTIĆA 7, 21000 NOVI SAD