

ECG4me

Personal mobile ECG-device

User Manual

EN

Personal mobile ECG-device ECG4me. User Manual

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This document applies to the Personal mobile ECG-device ECG4me, hereinafter referred to as *product* or *ECG4me*.

The document contains detailed information and instructions necessary for the correct and safe operation of the product. Failure to comply with these requirements may lead to incorrect results, equipment damage or injury.

To the user and/or patient – any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Conventions in this document



DO NOT. *Prohibition of the use of materials or methods of handling the product.*



WARNING. *Warning about the risk of danger to human life and health, or the risk of damage to the product.*



NOTICE. *Failure to comply with these recommendations may lead to incorrect results or failures.*

The names of the program interface elements (screens, windows, buttons) are in capital letters, for example, the SETTINGS window, the MINIMIZE button. The names of programs, commands, or values to be called are *in italics*.

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WARNINGS

-  *Do not use the product for purposes other than those specified in this document.*
-  *Do not leave the device unattended near children or people who are unable to express their intentions.*
-  *The product can only be used with the accessories provided by the manufacturer. Before use, make sure you have the necessary accessories.*
-  *Do not use the product in case of any doubts regarding its safety (the presence of traces of mechanical damage, improper operation, signs of unauthorized access or repair, damaged product's packaging).*
-  *The product contains a lithium battery. Do not apply excessive pressure to the amplifier housing. Do not close contacts. Do not throw into fire.*
-  *Do not use the product in conjunction with high frequency electrosurgical devices and electrical stimulators.*
-  *Do not use the product in the atmosphere with the presence of a combustible mixture of anesthetics with air, oxygen or nitrous oxide.*
-  *Do not use the product near to such powerful EM emission-source facilities as arc-welding machines, microwave ovens, X-ray units.*
-  *The automatic description of the ECG and the Report are not a diagnosis and may differ significantly from the medical opinion. Any diagnostic decisions should be made only by a doctor.*

Attention!

-  If the equipment has been used or stored at low ambient temperature and is then brought indoors, it (the equipment) must be allowed sufficient time (at least 4 hours) to warm up to room temperature and dissipate any moisture/condensation that may have collected within it.
-  Repair, modification and restoration of the product is performed only at the manufacturer.
-  The product is subject to disposal or destruction in case of confirmation of facts and circumstances that pose a threat to the life and health of citizens during the use or operation of the product.

1. INTRODUCTION

1.1 INTENDED USE

Personal mobile ECG-device ECG4me is a medical device that is intended for acquisition an electrocardiogram (*ECG*) at home or in medical institutions and diagnostic centers. ECG acquisition can be performed either independently by the patient or with the help of another person, for example a family member with or without medical education.

Field of application

- Cardiology;
- Rehabilitation;
- Personal medicine;
- Telemedicine;
- Functional diagnostics;
- Preventive medicine;
- Sports medicine, physical therapy and sports;
- Military, aviation, space and transport medicine;
- Medicine of disasters and extreme situations.

1.2 DESCRIPTION

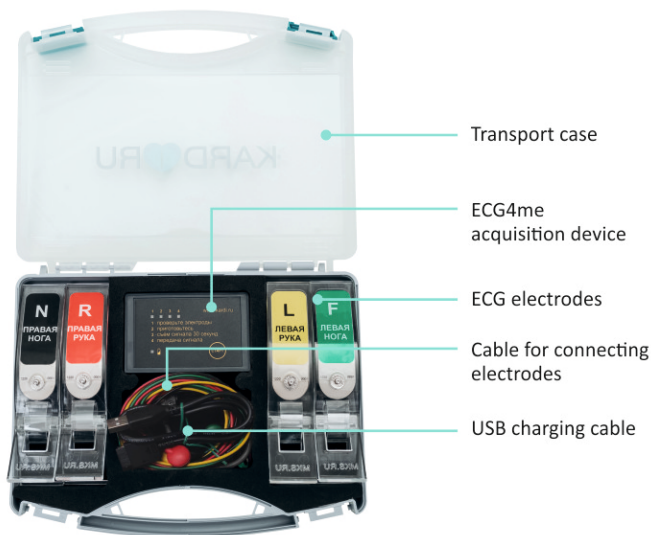
Personal mobile ECG-device ECG4me consists of a recording unit and cloud software for processing the examination, which provides access to the record and conclusion for the patient through the patient's personal account and for the doctor through the doctor's personal account.

ECG4me device (hereinafter referred to as the *device*) is an automatic device for recording a 6 or 12-channel electrocardiogram (*ECG*) in standard leads and transmitting it to cloud storage via the Internet channel.

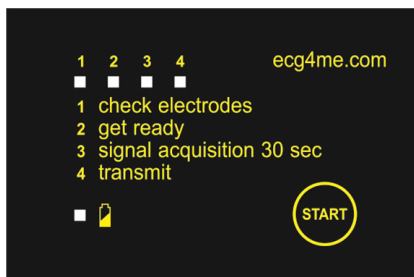
The ECG is automatically processed in the cloud storage. The full result of processing is always available in your personal account on the Internet website ecg4me.com (hereinafter referred to as *personal account*) or in the mobile application on your smartphone.

The automatic conclusion generated by the software is not a diagnosis, but indicates the features of the ECG.

2. SET




2.1 ECG4ME DEVICE



The front panel of the device is equipped with a START button to start ECG acquisition and light indicators to monitor the recording process. The meanings of the indicators are described in the section *Messages and indications on page 18*.

ECG4me device is equipped with a slot for a SIM card of a mobile operator and a universal connector for connecting a patient cable or a cable for charging the internal battery.

 *The orientation of the connector should be observed to avoid product damage. Markings on the cables indicate the top positions.*

2.2 PATIENT CABLE

The lightweight ECG cable allows the use of reusable or disposable electrodes with a snap connector.

Depending on the design, the product can be supplied with a cable for 6 or 12 standard leads.

ECG4me-12 (with 12-lead recording cable) allows you to get an ECG acquisition in 12 standard leads, as well as in 6 standard leads when selecting this mode in the mobile application or connecting a 6-lead recording cable to the device.

2.3 ECG ELECTRODES












Depending on the version, the set includes either 4 electrodes on the limb or 6 chest electrodes and 4 electrodes on the limb.

2.4 USB CHARGING CABLE

The charging cable is used to charge the device internal battery from a standard AC charger or from a PC USB port.

3. PREPARATION FOR USE

3.1 IMPORTANT INFORMATION

-  *The ECG4me device should be used to ECG acquisition only for yourself or family members registered in your personal account.*
-  *Consult your healthcare professional before using the device. Under no circumstances should you cancel or change the dosage of medications on your own.*
-  *Do not perform ECG acquisition immediately after swimming, drinking alcohol, smoking, exercising, or eating.*
-  *ECG acquisition should be carried out only in a sitting or lying position. You should not move or talk while taking an ECG.*
-  *The location for ECG acquisition should be selected away from sources of electromagnetic interference: operating refrigerators, electric motors, microwave ovens, electrical wiring (see section Conditions for use and disposal of the product on page 22).*
-  *Do not use excessive force when disconnecting connectors to avoid damage (see section Examination on page 14).*
-  *If the Internet channel of a cellular operator is used to transmit an ECG examination, then the SIM card must be active (not blocked) to conduct the examination. To clarify the balance, you should contact your cellular operator or ECG4me support service when using the SIM card that came with the device.*
-  *The device can be used in roaming. To clarify the possibilities and restrictions on the use of roaming services, contact your mobile operator.*
-  *The patient is not required to provide any personal information. If the patient provides his personal data, then he confirms that he is familiar with local laws in the field of personal data protection.*
-  *It is necessary to periodically check the condition of the device and its accessories according to the instructions in the section Maintenance procedure on page 16.*
-  *Reuse of reusable electrodes is allowed only after disinfection.*

3.2 PERSONAL ACCOUNT

To enter your personal account you should:

- Login to the ecg4me.com site using a computer with an Internet browser installed, for example, Microsoft Internet Explorer, Google Chrome, Firefox, Opera, Safari, or open a ECG4me.com mobile application.
- You need to log in on the main page of the site or in the mobile application.
- To create a personal account, you should register. To activate and confirm registration, as well as to link the device to your personal account, you may need to contact support. Support contacts are listed on the website.

3.3 INSTALLING A MOBILE OPERATOR SIM CARD

If your device can transmit ECG through the network of a mobile operator, then to implement this feature, you need to install a Nano-SIM format SIM card with an activated tariff plan that provides a data service. When selling a device with a SIM card, it is installed into the device by the support service.



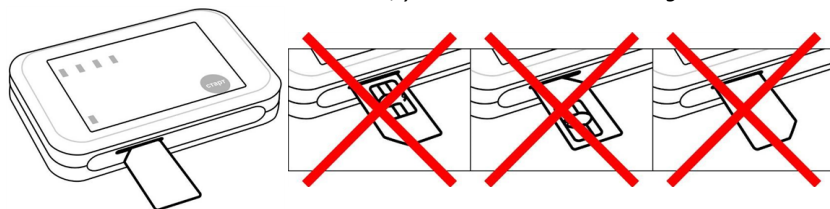
Insert or remove the SIM card when the device is turned off.

Before inserting the SIM card, disconnect the patient cable/charger. The SIM card is inserted face up (contacts down). The SIM card must be pushed into the slot until it locks.

Use tweezers to remove the SIM card. After pressing, the ejector built into the device will work, and you can grab the card.



A SIM card can be installed in the device during pre-sale preparation of the device and hardwired. In this case, you cannot remove or change the SIM card.



3.4 MOBILE APPLICATION INSTALLATION

Two mobile applications are available: for the doctor and for the patient.

The patient mobile application is designed to view examinations of the patient and his family members.

A mobile application for a doctor is designed for remote monitoring of examination from different patients and several ECG4me devices. ECG aquisition using a doctor mobile application is NOT possible.

ECG aquisition is carried out ONLY using the patient's mobile application, even if the examinations is performed by a doctor, for example, when visiting the patient's home. For a doctor, this application has a special "diagnostic room" mode for screening patients. To enable this mode, contact support ECG4me.

Mobile apps are available for iOS and Andriod devices and can be installed from official app stores.

OS Android

Patient mobile application	https://play.google.com/store/apps/details?id=ru.mks.kardi&hl=ru
Doctor mobile application	https://play.google.com/store/apps/details?id=ru.mks.kardi_doctor&hl=ru

iOS (Apple)

Patient mobile application	https://apps.apple.com/ru/app/id1111486417
Doctor mobile application	https://apps.apple.com/ru/app/id1556459760

For the application to work you need:

- On the mobile device on which the application is used, enable the Bluetooth protocol.
- On the "Settings" page of the mobile application, set permission to access the ECG4me device (tap the "Give permission" button).
- The device will be added to the list on the "Devices" page in the mobile application.

4. GETTING STARTED

4.1 WORKING MODE

ECG4me, depending on the modification of the device (4G or BLE), supports the following modes of acquisition and data transfer.

Mode 1. Built-in SIM card

Used in ECG4me devices with built-in 4G modems.

The device recording and transmits examination data to your personal account automatically, immediately after completion of ECG registration via the Internet channel of a cellular operator, using a SIM card installed in the ECG4me. To perform an examination in this mode, simply apply the electrodes and press the “Start” button on the device.

After completing the ECG acquisition, the device will transfer the examination to the personal account of the patient and the doctor, if the patient is under the supervision of a doctor. The subject is not required to take any action.

This mode is convenient for quickly examination, for example, for patients who cannot or do not want to use a mobile application.

If the device is unable to transmit an ECG signal within 30 seconds (weak mobile signal, SIM card blocked, etc.), it will turn off, but the ECG recording will be saved in the device memory. The next time you turn on the device, it will immediately try to transmit all saved ECGs.

The device memory can store up to 100 examinations. Once the memory is full, examinations will be deleted in order, starting with the oldest.

Mode 2. Mobile application

To operate in this mode, the ECG4me device should be connected via Bluetooth to a mobile device (for example, a phone or tablet) on which the ECG4me.com mobile application is installed.

In this mode, the user controls the device from the smartphone screen.



After connecting to the device, the mobile application allows you to start examination, monitor the ECG and monitor the signal quality. During the examination, the ECG is displayed in the mobile application in real time.

In the application in monitoring mode you can:


1. Change the ECG visualization speed to 12.5 mm/s, 25 mm/s or 50 mm/s.
2. Change the ECG amplitude 2.5mm/mV, 5mm/mV, 10mm/mV or 20mm/mV.

After completing the ECG acquisition, the examination is transmitted via the Bluetooth protocol and saved in the memory of the user's mobile phone. Further, if the phone is connected to the Internet, the examination is transferred to cloud storage and the conclusion becomes available in the patient's and doctor's personal account.

The mobile app can also store up to 100 examinations. If this number is exceeded, examinations are deleted in order, starting from the oldest. The entire queue of unsubmitted examinations is available for viewing in the mobile application. If the mobile application contains unsent examinations, then immediately after connecting the smartphone to the Internet, the examinations will be automatically sent to the server ecg4me.com. A few seconds after sending, the data will become available in the patient's personal account.

-  *Typically, transmission via Bluetooth is faster, uses less battery power, and costs significantly less. Therefore, even if your device can transmit ECG through your mobile operator's network, it is recommended that you connect it to your mobile device.*
-  *All examinations for the last 5 years are stored in the patient's personal account without restrictions on the number of examinations.*

4.2 RULES FOR APPLYING ELECTRODES

-  *It is prohibited to impose the product on damaged areas of the skin.*

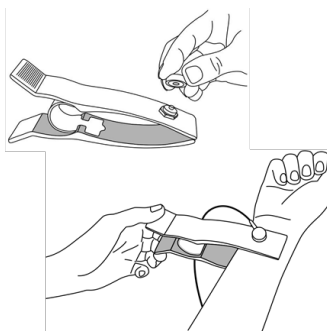
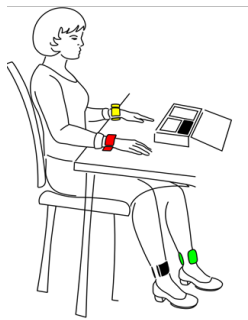
Skin preparation

To improve the quality of the recorded ECG, it is recommended to clean the skin at the sites where the electrodes are applied with a damp cloth soaked in water. In the case of using reusable electrodes, the contact plates of each electrode should be moistened with ECG spray, saline solution or tap water.

When using disposable ECG electrodes, the skin in the areas where the electrodes are glued should be wiped dry after cleaning.

ECG acquisition in 6 standard leads

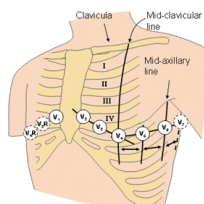
ECG acquisition in 6 standard leads is performed while sitting. Electrode contact pads or disposable electrodes should be placed on the inner surfaces of the ankles and wrists.




It is necessary to put the electrodes on your legs first: black – on the right leg, green – on the left leg; then on the hands: yellow - on the left hand, red - on the right hand. Make sure the patient cable leads are connected to the appropriate electrodes.

ECG acquisition in 12 standard leads

ECG acquisition in 12 standard leads is carried out in a sitting or lying position. Electrodes can be applied independently or with the help of an assistant. The limb electrodes should be placed as described above, the chest electrodes should be placed on the chest according to the scheme.




Marking of the electrodes	Color of wire and electrode	Position on body
R	red / red	right arm wrist
L	yellow / yellow	left arm wrist
F	green / green	left leg ankle
N	black / black	right leg ankle
C1	white / red	IV intercostal space along the right edge of the sternum
C2	white / yellow	IV intercostal space along the left edge of the sternum
C3	white / green	V edge between C2 and C4
C4	white / brown	V intercostal space on the left midclavicular line
C5	white / black	left anterior axillary line at the horizontal level C4
C6	white / purple	left mid-axillary line at C4 level

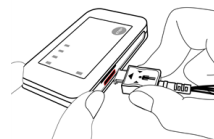
 *A neutral (**GND**) electrode should always be connected. The quality of the recorded ECG in all leads depends on the quality of the placement of the neutral electrode.*

4.3 EXAMINATION

1. Connect the patient cable to the device.

Check that the  patient cable is connected to the device. If necessary, insert the cable into the connector until it clicks into place.

Depending on the type of patient cable, ECG examination in 6 or 12 standard leads is automatically selected.



2. Place the electrodes on the patient's body.

Prepare the skin and apply electrodes as described in section *Rules for applying electrodes on page 12*.



It is prohibited to impose the product on damaged areas of the skin.

3. Run the mobile application (if used).

Run the mobile application. In the list of available devices, select the serial number indicated on the device case.

If the connection is successful, the blue “Signal Transmission” indicator on the device will light up.

4. Start the acquisition.

Press the START button .

The device automatically controls the quality of electrode application. If there is poor contact, the “check electrodes” indicator will light red. In this case, it is necessary to correct the electrodes.

The mobile application implements visual quality control of electrode application.

If the contact quality is good, the yellow “get ready” light will light up for 5 seconds. You should sit comfortably, put your hands on your knees, relax your muscles.

Then the green indicator “receive signal for 30 seconds” will light up and the device will switch to ECG recording mode. For 30 seconds you need to sit or lie relaxed, motionless, breathe evenly, and not talk.

5. Completing registration and transferring data to the server

Once registration is complete, the blue “signal transmission” indicator will light up. Electrodes should be removed from the patient and cleaned. The device should not be turned off. As soon as the data is transferred to the server for processing, the device will turn off automatically.

If the device cannot transmit an ECG signal within 30 seconds, it will turn off and the ECG recording will be saved in the device memory. The next time you turn on the device, it will immediately try to transmit all saved ECGs.

6. Cancel current registration

To cancel the transfer, as well as to stop the operation of the device at any stage, hold down for 6 seconds until a characteristic sound signal is heard. In this case, the device will turn off and the current ECG will be lost.

7. Obtaining a conclusion

After each acquisition, conclusions are automatically generated. Conclusion reports become available in your personal account on the ecg4me.com website or in the mobile smartphone application a few seconds after the acquisition. Reports are available for viewing, printing or sending via instant messengers to the attending physician.



The automatic description of the ECG and the Report are not a diagnosis and may differ significantly from the medical opinion. Any diagnostic decisions should be made only by a doctor.

5. MAINTENANCE

5.1 MAINTENANCE PROCEDURE

To maintain the product in good condition, regular full maintenance is required.

Type of service	Periodicity
checking the completeness of the product	daily, just before work
checking all components of the product and PC for mechanical damage and malfunctions	daily, just before work
removal of dust and moisture from the external surfaces of the product	daily, just before work
cleaning of reusable electrodes	daily, immediately after completion of work
disinfection of reusable electrodes	immediately after examination or sequential examinations for one patient
cleaning and disinfection of device, including cables	daily, immediately after completion of work

5.2 CARE

Cleaning the device body and patient cable


1. Check cables for damage and signs of wear. Make sure all connectors are functioning properly.
2. Gently wipe the product, including cables, with a cloth lightly moistened with one of recommended disinfectants.
3. Clean the outer surface of the product body with a soft, slightly damp (not wet) cloth. The cable should be wiped starting from the middle in 20 cm sections at a time to avoid deformation of the cable insulating coating. For additional cleaning, it is acceptable to use a non-alkaline household cleaner or a 50% alcohol solution.
4. Remove any remaining cleaning agents.




Do not allow liquid to enter the product. If liquid gets into the connectors, it is necessary to dry them with a stream of warm air, and then check the operation of the product.

Cleaning ECG electrodes

1. Rinse the electrodes with warm water to remove any remaining gel.
2. Wipe the electrodes with a cloth lightly moistened with disinfectant.
3. Wipe the connector contacts with a cotton cloth moistened with a weak (less than 10 %) alcohol-containing solution.

 *It is forbidden to use abrasive agents, ultrasonic devices, sharp objects (scalpels, needles, tweezers, etc.) to clean the electrodes.*

 *Do not chlorinate electrodes, use strong disinfectant solutions (for example, based on acetone), as this will lead to corrosion.*

 *Do not sterilize the product.*

5.3 TESTING AND CALIBRATION

















Testing and calibration of products in the production process ensures parameters of the product throughout the life cycle. Contact the manufacturer if recalibration is necessary.

6. MESSAGES AND INDICATIONS





6.1 SOUND SIGNALS

Signal	Signal description
One short beep	Transition between modes: check electrodes / get ready / acquisition / transmit data; Short press on the button; Turn off the device.
Two short beeps	Connecting to a device via bluetooth; Disconnect from the device.
Three short	There is not enough space in the device memory
One long beep	An error has occurred. The error code is displayed using blinking indicators (see <i>Error code indication on page 19</i>).

6.2 DEVICE STATUS INDICATION

































Indicator	Value	Operator actions
   	The red indicator “Check electrodes” is on	Make sure the electrodes are installed correctly. If necessary, moisten the skin under the electrodes with an electrically conductive solution.
   	The yellow indicator “get ready” is on	Aquisition will start after 1-2 seconds.
   	The green indicator “signal acquisition 30 sec” is on	Wait until the end of the acquisition.
   	<ul style="list-style-type: none"> Transferring the examination on the server Bluetooth connection 	Wait until the end of the acquisition.
Battery indicator is green	The battery is sufficiently charged	
Battery indicator blinking red	Low battery (charge level is below 15%)	Charge the battery. If the registration process is ongoing, it is acceptable to wait until the procedure is completed.
Battery indicator is red	Battery charging in progress	Wait for the end of the charging process

6.3 BATTERY STATUS INDICATION

Indicator	Value	Operator actions
	Battery charge is sufficient for operation	Conduct examinations as usual
 blink	Battery charge less than 15%	Charge the battery
 lit	Charging in progress	Wait for the process to complete
	Charging process complete	Disconnect the charging cable

6.4 ERROR CODE INDICATION

Flashing indicators together with a beep indicate an error

Signal	Error code	Description
   	0	Battery is low
   	1	Device error
   	2	Read / write error
   	3	Analog to digital converter error
   	4	Built-in battery error
   	5	Modem error
   	6	SIM card error
   	7	Unknown operator

7. TROUBLESHOOTING

Fault	Probable reason	Method of correction
The device does not turn on	Short time for pressing the START button	Press and hold the button for at least 2 seconds
	Battery is discharged	Charge your device
	Device rest required	Connect the power cable to the device. DO NOT CONNECT the other end of the cable to the power supply. On the cable connector on the device side, find the hole indicated by the arrow. Using a needle, press the reset button in this hole until the device lights up.
The mobile application does not connect to the ECG4me device via Bluetooth	Bluetooth is not enabled on the mobile device on which the mobile application is used	Turn on Bluetooth on your mobile phone
	The mobile application settings do not provide permission to access the ECG4me device	On the "Settings" page in the mobile application, click the "Give permission" button
	The device is not added to the list of devices in the mobile application	On the "Devices" page in the mobile application, click the "+" button and add a device
	Devices based on older versions of Android require permission to access geolocation when connected via Bluetooth	Allow the application to access geolocation in your phone settings and try again
The indicators on the ECG4me device flash quickly alternately	Device rest required	Connect the power cable to the device. DO NOT CONNECT the other end of the cable to the power supply. On the cable connector on the device side, find the hole indicated by the arrow. Using a needle, press the reset button in this hole until the device lights up.
The yellow indicator "1" is flashing	No contact of electrodes with skin	Wipe the skin under each electrode with a damp cloth and press the electrode to the skin using the fasteners
	Patient cable not connected	Reconnect the patient cable
	Patient cable is damaged	Replace patient cable

Fault	Probable reason	Method of correction
ECG transmission error: one long beep sounds, the indicator displays an error code	The device is out of range of the mobile network	Make sure that the mobile network is available and working in this location. Change location if necessary
	There are not enough funds in the device SIM card account to transfer data to the server	Check the availability of funds in your device SIM card account. Top up your account if necessary Top up your account if necessary
	The device is discharged	Charge your device
There is a lot of noise on the ECG	Poor electrical contact between device and patient	Check the connection of the patient cable, check the quality of electrode application
	Patient movements during ECG signal recording	Repeat the examination. During ECG acquisition, sit relaxed, do not move, breathe evenly, DO NOT TALK
	There is a source of strong electromagnetic interference nearby	Select a location away from sources of electromagnetic interference: running refrigerators, electric motors, microwave ovens, electrical extension cords and outlets, and repeat the survey

If the problem persists, contact the supplier or manufacturer.

8. CONDITIONS FOR USE AND DISPOSAL OF THE PRODUCT

8.1 ELECTROMAGNETIC COMPATIBILITY

ECG4me meets the requirements of the standard regarding immunity to electromagnetic interference and emitted radiation. However, special precautions must be taken: do not use mobile (cellular) phones or other devices that generate strong electric or electromagnetic fields near the operating product. This may interfere with the operation of the product and create a potentially unsafe situation. It is recommended to maintain a distance of at least 3 m. If the distance is less, you need to make sure that the product is working correctly.

8.2 DISPOSAL

Before you dispose of any item, you must ensure that all materials that have been in contact with the patient are not contaminated. You may have to thoroughly clean and disinfection before disposal.

8.3 WARRANTY

The manufacturer hereby guarantees that the product will be free from any defects in materials and workmanship (except for consumables) for a period of one year from the date of delivery. This warranty does not apply to any damages caused by misuse, modification, and noncompliance with operating instructions. If this product requires repair under our warranty, the customer shall notify the supplier or manufacturer about the defects and send the product adequately packed in a shipping container to the supplier or manufacturer for the purpose of inspection and service.

ECG4me personal mobile ECG-device

Getting started

Please read the complete instructions inside before using for the first time.

- 1 Wet the metal electrode plates.
While sitting, put on the electrodes.

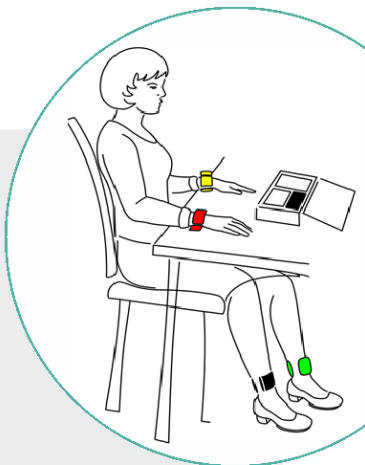
Black – on the right leg,

green – on the left leg.

yellow – on the left hand,

red – on the right hand.

The electrode plates should be on the inner surfaces of the ankles and wrists.



If the indicator is red, charge the device.

- 2 Turn on your device.



- 3 Follow the indicators on the device body



Poor contact of electrodes with skin.
Moisten the electrode plates and press firmly onto the skin.



Get ready. Sit comfortably:
place your hands on your knees, relax your muscles.



ECG acquisition in progress.
Sit relaxed, do not move, breathe evenly.



Remove the electrodes – acquisition is complete

- 4 Detailed results will be available in your account on the website www.kardi.ru or in the mobile application.



www.kardi.ru