WECARDIO
TECHNOLOGIES

ECG EVENT RECORDER

Wecardio UN

BORSAM Biomedical
A/3

TO USE THE ECG EVENT RECORDER

You will need:
> A Smartphone or an iPad(with Bluetooth & Wifi/Data on)
> The ECG Event recorder
> The AIRCardio APP
<Note: the smart phone shall support Bluetooth 4.0, Android 4.3+ or IOS>

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Copyright Declaration:

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Declaration of Conformity:

Conformance to Standards – non-clinical testing demonstrated conformance to

voluntary safety IEC60601-1 and to IEC60601-1-2-2014 Class IIa.

Warning: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a

Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the

interference by one or more of the following measures:

☐ Reorient or relocate the receiving antenna.

☐ Increase the separation between the equipment and receiver.

☐ Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

☐ Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

BORSAM Biomedical Instruments Co., Ltd.'s Quality System conforms to21 CFR 820 and ISO13485:2016

Danger :

Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

Contraindications:

There are no potential adverse effects of the ECG-Event Recorder on health.

Description:

This guide describes the ECG Event Recorder to use, and related cleaning and maintenance operations.

The metal sheets on the side and front is the position of application part.

Patients can safely use the ECG signal collection function of the device; The device does not have unsafe functions.

Classification:

Class II / Internally powered equipment;
Type BF applied part;
IP22;
Continuous operation mode

TABLE OF CONTENTS

OVERVIEW:

[INTENDED USE]

The produce is intended to use at temperature of + 5 ℃ ~ + 40 ℃,relative humidity of 15% to 93% (without condensation). ECG event recorder is suitable for real-time ECG signal acquisition, Storage and wireless transmission of patients with Arrhythmia.

Note: The above indications for use of the ECG Event Recorder monitoring stations is to provide a reference for medical diagnosis, not a replacement for diagnostic clinicians.

[ACCESSORIES]

- 1x ECG Event Recorder
- 1x Strap
- 1xUSB Charger cable
- 1xUser manual
- 1xWarranty Card
- 1xBox

[SPECIFICATIONS]

Model: WeCardio UN ; WeCardio WF
Size: 87mm×49mm×7mm ;
90mm×50mm×10mm
Weight（with battery）:33g ; 38g
Carton:PC plastic
Battery:lithium ion battery/d.c.3.7V
Working hours:24 hours
Bandwidth:0.5Hz – 40Hz

Input Impedance:≥ 3.0 Mohm
Input range:0.05～6 mV
Sample Rate:500 Hz
Sampling precision:12 bits
Transmission mode:Bluetooth 4.0
Recording: single-lead ECG

[OPERATING CONDITIONS]
Temperature: +5℃ to +40℃
Humidity: 15% to 93% RH (without condensation)
Pressure altitude: 700 hPa to 1060 hPa

[STORAGE AND SHIPPING CONDITIONS]
Temperature: -5℃ to 35℃
Humidity: 25% to 85% RH (without condensation)
Pressure altitude: 700 hPa to 1060 hPa

TO GET STARTED:

[DOWNLOAD APP]

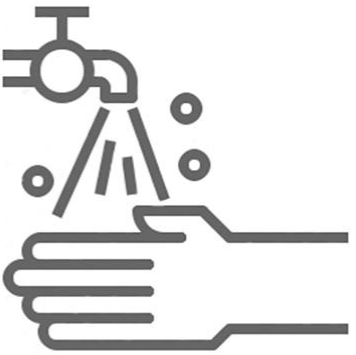
1.For Android system:
Go to “Google Play” and search the “WECARDIO” .
Use the download link:
http://en.wecardio.com/download/wecardio.apk

2.For Apple IOS system:
Go to “App Store” and search “WECARDIO”

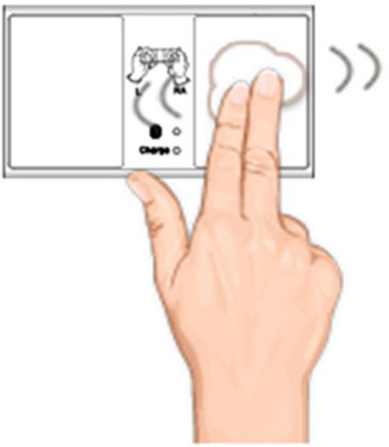
3.Scan the following QR Code

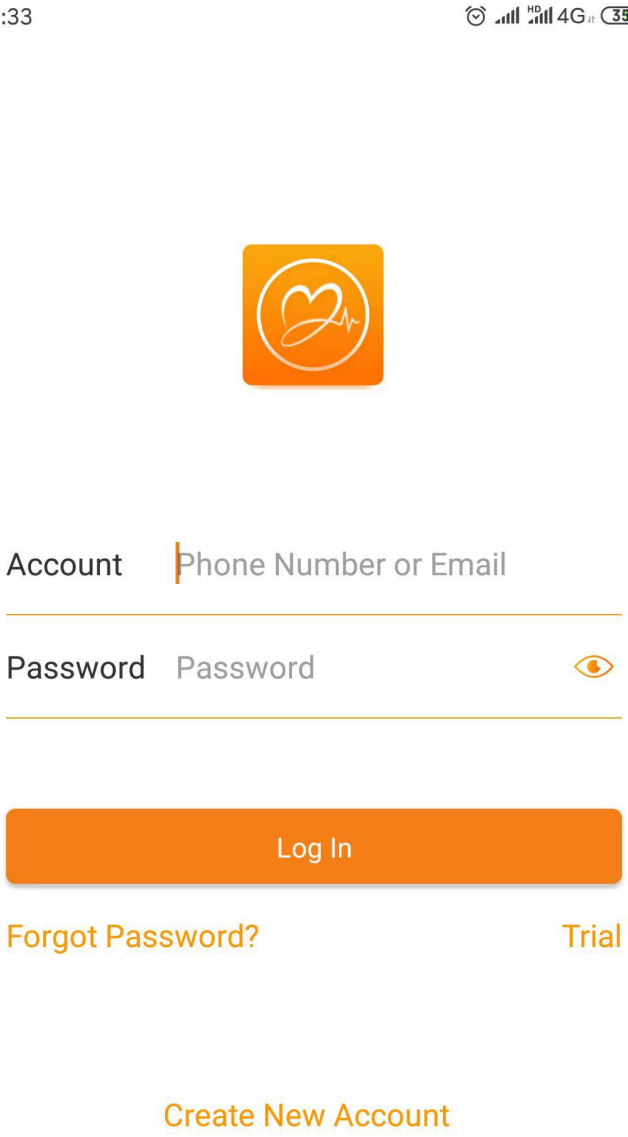
[PREPARATION BEFORE USE]

1.It is best to clean your hands before using the device.



2.If the device has not been used for a long time or is a newly purchased device, it is recommended to gently wipe the metal surface of the device with a damp cloth.





Register free with your email.

2.Sign In

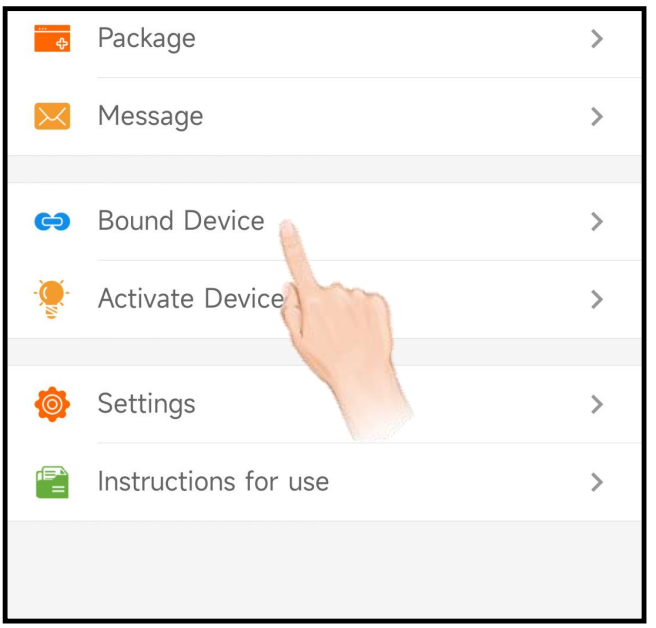
If registered already, input the user name and password directly to access.

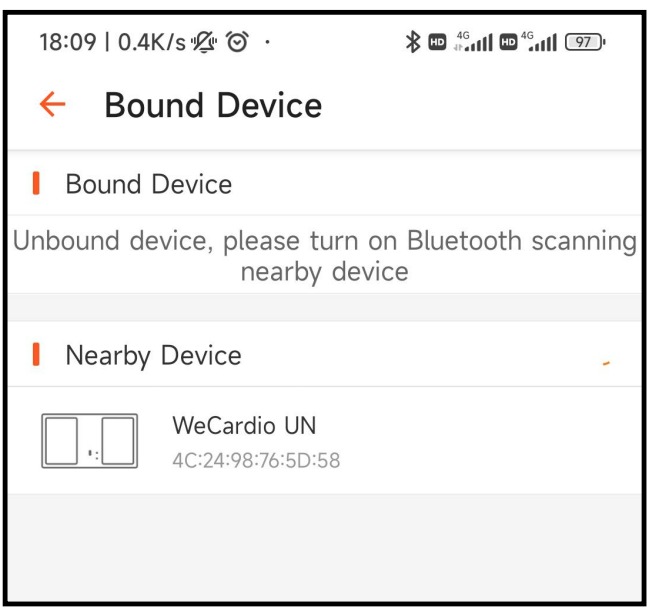
Click the > on the right of the user name bar, you will find all the users name ever log in. You can select or add.

3. Try Out

Please click “Try Out” for checking. (It is for testing only, cannot feedback any results.)

4. Enter to the Application and open the bluetooth, then bind the device under the "Bound Device" interface.

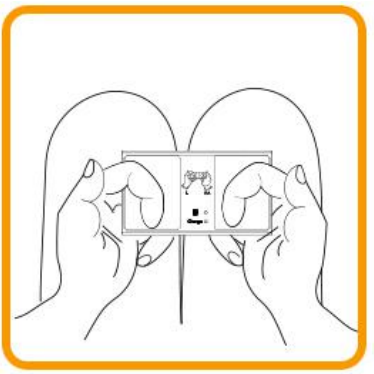


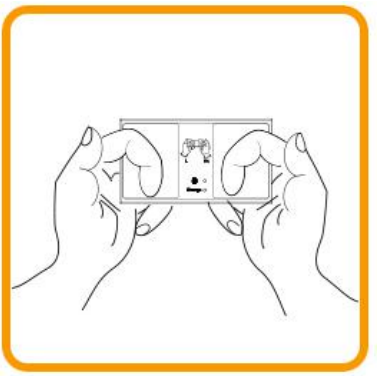


[ARRHYTHMIA CHECK]

1.Open the app, select "Arrhythmia".

2.Method one: hold the electrode with both hands and put it on your legs or table.

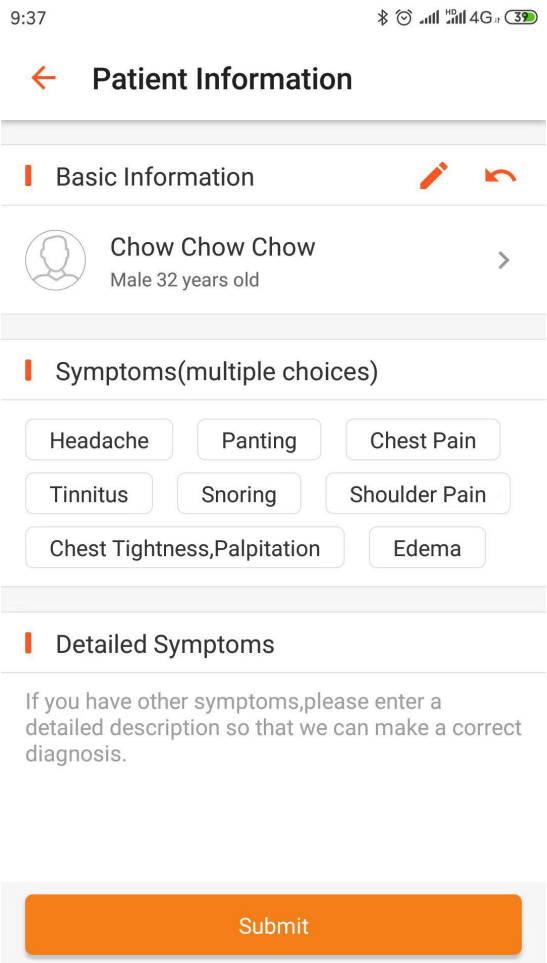




3.Method two: the right hand grip electrode pads, the side of the electrode below the nipple, the body naturally by the back.

4.No talking, remain static when check.

5.When finished, select the symptoms or change patient information in the app, the system will automatically generate reports.

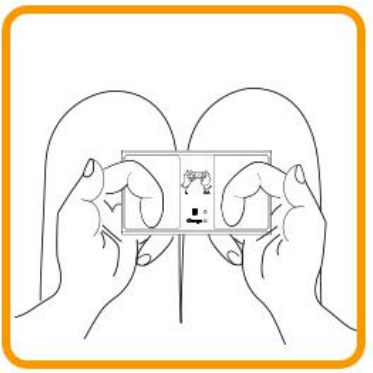


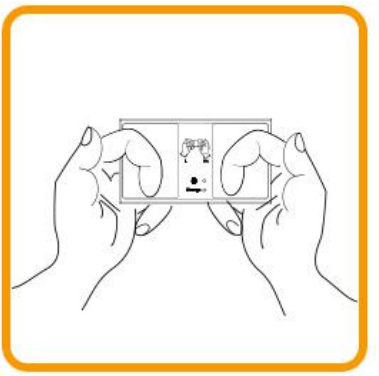
Note: the patient's information is the current login account information, which can be selected by clicking on the user information or manual changes.

[ISCHEMIA CHECK]

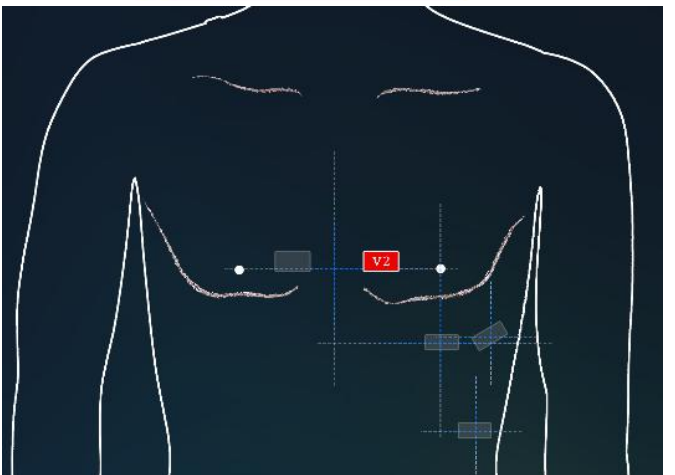
1.Open the app, select " Ischemia ".

2.hold the electrode with both hands and put it on your legs or table.



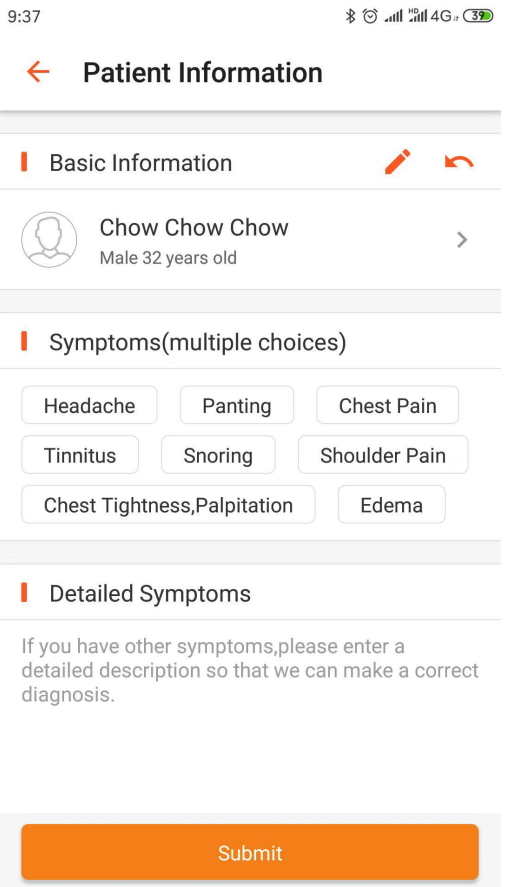


3.Keep clamping the device with right Forefinger, and put side electrode at the 6 position (I II V1 V2 V4 V6) one by one in the picture, if the light don't show red, please slightly wet the skin. If ready, please click "start" to check 5 times accordingly.



3.No talking, remain static when check.

4.When finished, select the symptoms or change patient information in the app, the system will automatically generate reports.

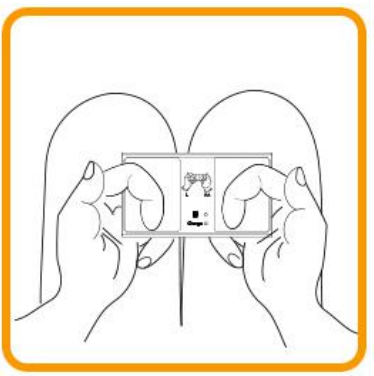


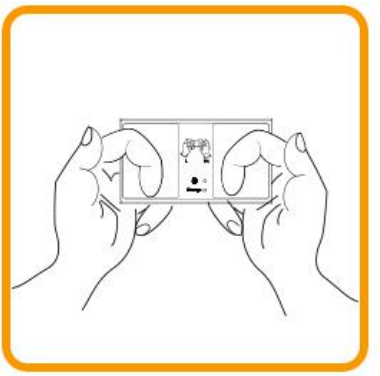
Note: the patient's information is the current login account information, which can be selected by clicking on the user information or manual changes.

[ANS Evaluation CHECK]

1.Open the app, select " ANS Evaluation ".

2.Method one: hold the electrode with both hands and put it on your legs or table.

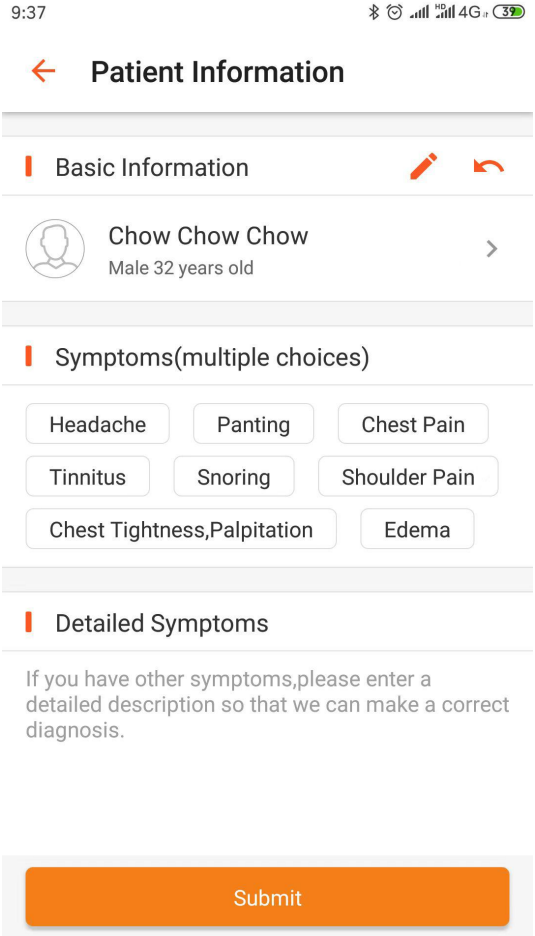




3.Method two: the right hand grip electrode pads, the side of the electrode below the nipple, the body naturally by the back.

4.No talking, remain static when check.

5.When finished, select the symptoms or change patient information in the app, the system will automatically generate reports.



Note: the patient's information is the current login account information, which can be selected by clicking on the user information or manual changes.

[RECORDING LIST]

a).Local Recordings:

Local Recordings is the data stored in your mobile phone. Please note the local recordings will be removed when clearing the phone cache.

Pull down the page to get date updated.If there are checking results returned, it will show icon with different color. Green: stable heart rate; Red: arrhythmia, please double check; Yellow: Artifact, please check again.

Note: we suggest to go hospital for detailed checking when the results stick to red even though you keep not moving and the ECG waveform is flat.

Click one recording to get details:

a.Moving the cursor to the left or right to view waveform

b.Zooming to view the waveform

c.Clicking “PDF”to download the report.Users can also mail to the report to the doctor.

[APP Setting]

Go to "set" (shown in the bottom of the page) and click"record set".

a.Recording Time

Choose as follows: 10 seconds, 30 seconds, 40 seconds, 60 seconds.

b.HR display

On or Off

c.ANS Recording Length

Choose as follows: 2 minutes, 5 minutes.

[NOTICE]

The computer or any device to connect the USB charging cable must be in accordance with the IEC60950 certification.

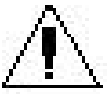
[WHO SHOULD USE THE DEVICE]

In order to use this device, you must be able to perform all of the following:

- Understand principle of operation described in this manual
- Speak and understand English
- Place the ECG Event Recorder in your hands or on your chest, hold it for at least 30 seconds
- Operate a ECG Event Recorder and the Web Center application
- Operate simple push-buttons

Due to the possible seriousness of the abnormal heart rhythms that can be associated with these conditions, persons with the following conditions should consult their physician before using this device:

- Coronary heart disease
- Valvular heart disease
- Heart transplant
- Heart failure

[WARNING] 

ECG Event Recorder is not a diagnostic device. This single lead ECG, which is measured using ECG event recorder, should not be used for diagnostic in comparison to the standard 12 lead ECG recorder obtained with typical electrode placement.This device should not be used with pacemakers or implanted defibrillators and cannot predict or diagnose a heart attack or be used for chest pain monitoring.The ECG Event Recorder is not a defibrillation-proof device.
To prevent fire or shock hazard, do not expose the unit to rain or moisture. Refer servicing to qualified personnel only.

The device is charged by USB with voltage DC 5V. Please use charger passed GB 9706.1 or IEC 60601-1. Please note that the device will not working properly during charging.

To avoid poor data recordings, please recharge the device when mobile telecom equipment indicates low power of the device.

The Software working together with the ECG Event Recorder is ECG Holter Analysis system, Model eCardio7.0, which is composed of special analysis module & transmission management module. This analysis system is not a part of the ECG Event Recorder.
The device will not be used in surgical operation, and not used together with high frequency electrotome.

Equipment may not be used with acidic or alkaline etc corrosive liquid to clean.
The user's can't repair the device by themselves.

[REGULATORY COMPLIANCE]
Conformance to Standards -
TEST REPORT IEC60601-1, IEC60601-1-11 & IEC 60601-2-25 for
Medical electrical equipment.
This device complies with the FCC Rules and with EMC & R&TTE. Also, it passes the Biological Evaluation Test and has CE mark.
BORSAM Biomedical Instruments Co., Ltd.’s Quality System conforms to ISO13485 issued by TUV SUD.

MAINTENANCE:

[BATTERY]

Caution:

Use only rechargeable Lithium batteries.

Risk of explosion if battery is replaced by an incorrect type.

Dispose of used batteries according to the instructions.

1. Please contact us if battery replacement needed.
2. Charge the battery with the certified charging cable provided by BORSAM.
3. Charging the device: please change the device with dedicated charging cable; charging voltage: DC 5V, charging current: 115mA
4. **Device should be charged every 2 months when not in use to maintain battery life.**

[CARING FOR YOUR ECG EVENT RECORDER]

Do not open or attempt to repair your ECG Event Recorder by yourself. Only authorized service personnel may repair.

Do not drop your ECG Event Recorder or subject it to severe impacts. Bending the body can damage the circuitry. Do not use extreme force when pressing the display or keys.
Do not use solvents to clean your ECG Event Recorder. Use only a soft, dry cloth.

[ENVIRONMENT]
Keep away from extreme heat. Do not leave it on the dashboard of a car or near a heater. Do not leave it in any place that is extremely damp or dusty.
As this product is not waterproof, do not use it or store it at place where fluids such as water can splash onto it. Raindrops, water spray, juice, coffee, steam, perspiration, etc. may also cause a malfunction.
Keep accessories that might be swallowed away from children.

[PRECAUTIONS]
Warning: Dispose of all used batteries in a proper waste disposal in accordance with local regulation. Used batteries must not be discarded in the normal trash.

[PREVENTIVE MAINTENANCE]

The following simple preventive maintenance tasks should be performed monthly to ensure continued performance of the device at maximum capacity, and to reduce the possibility of a failure.

[CLEANING]

- Clean outside of the device only, using a lint-free dry cloth.
- Do not allow any liquid to enter the device, and avoid pouring water or other liquids on the device while cleaning.
- Never use a brasives such as wire-wool or metal polish.
- During cleaning, make sure you do not expose the device to temperatures in excess of 45°C(113°F).

[EXPLAIN]

a. The device requires no calibration.

b. The device is not repairable and contains no user serviceable parts.

c. No modification of this equipment is allowed.

d. The user must check that the equipment functions safely and see that it is in proper working condition before being used.

e. Disposal
Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact your local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

f. Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

g. g.Do not position the equipment so that it is difficult to operate the disconnection device.

h. Magnetic and electrical fields are capable of interfering with the

proper performance of the XXX. For this reason make sure that all external devices operated in the vicinity of the XXX comply with the relevant EMC requirements. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

i. Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (See IEC 60601-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system complies with the requirements for medical electrical

systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

[Situation when patients operate the device by himself/herself]

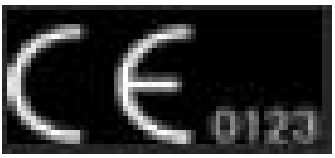
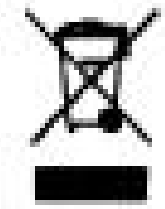
1. Patients is the operator
2. During usage, patients only need simply clean the device with clean soft cloth
3. Patients can only set the patients information
4. Repairing device need to be done by manufacturer, patients cannot repair it by himself/herself
5. Patients cannot replace battery by himself/herself

[Maintenance can be done by Patients]

1. Clean the device with soft cloth which is slightly wet in the mix liquid of water and mild detergent

2. Please change the device with dedicated charging cable and certified compatible adaptor

[EQUIPMENT SYMBOLS]

Symbol	Description
	Type BF applied part
	Symbol for “CAUTION, CONSULT ACCOMPANYING DOCUMENTS”
	Complies with the Medical Device Directive of the European Union.
	Waste Electrical and Electronic Equipment (WEEE) It is the responsibility of the end user to dispose of this equipment at a designated collection point for recycling.
	Year of Manufacture
SN	Serial Number
	Symbol for

	“MANUFACTURER”
EC REP	Symbol for “AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY”
WECARDIO TECHNOLOGIES	Trademark
	Refer to instruction manual / booklet
IP22	Protected against access to hazardous parts with a finger and against vertically falling water drops when enclosure tilted up to 15°

[FAQ]

Questions	Solutions
Indicator lights do not turn on	Please check whether your hands touch on the 2 electrode sheets
	Please check whether the electrodes are put at the right position (with one electrode clamped by right hand and the side electrode put on the chest).
	Please slightly wet your skin with alcohol if skin is too dry.
	Please make sure the side electrode touch the skin directly if with too much chest hair.
	Please change a new battery or recharge the device if power off.
Always show waiting and cannot enter to ECG check page	Please check whether Bluetooth on
	Log out and re-enter
	Please restart the Bluetooth of the phone
Server does not feedback the test result	Please check the network connection is fine; check whether you are in the “Try Out”

	page.
Cannot turn on the device: indicator lights do not turn green	If the green light do not on when start the device, please charge the device on time; or send back to the manufacturer for repairing.
Cannot transmit data	1. The light will turn blue when transmitting data. If not, then it cannot transmit data 2. The terminal device must support Bluetooth 4.0, otherwise cannot transmit data 3. Must completely install the related APP. And the device can be found on the terminal device when search the Bluetooth.
ECG waveform baseline drift and strong interference	Please strictly follow this manual to complete the ECG recording; please keep away from the large electrical equipment or other electromagnetic interference, such as electric blanket, heating pad and computer

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electromagnetic emissions		
The [FG9131] is intended for use in the electromagnetic environment specified below. The customer or the user of the [FG9131] should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The [FG9131] uses 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 [FG9131] is suitable for use in all establishments other than

		domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The [FG9131] is intended for use in the electromagnetic environment specified below. The customer or the user of the [FG9131] should assure that it is used in such an environment			
Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-	±8 kV contact ±15 kV	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are

4-2	air		covered with synthetic material, the relative humidity should be at least 30 %
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity
The [FG9131] is intended for use in the electromagnetic environment specified below.

The customer or the user of the [FG9131] should assure that it is used in such an environment			
Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the [FG9131], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz

			where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [FG9131] is used exceeds the applicable RF compliance level above, the [FG9131] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [FG9131]. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the [FG9131]

The [FG9131] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [FG9131] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [FG9131] as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m	
	80MHz to 800MHz $d=1.2\sqrt{P}$	**800MHz to 2.5GHz** $d=2.3\sqrt{P}$
0,01	0.12	0.23
0,1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

For transmitters rated at a maximum output

power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.