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User's Manual

ER2 ECG recorder

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1. The basics

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

1.1 Safety

⚠ **Warnings and Cautionary Advices**

- Before using this equipment, please read this manual carefully and fully understand the warnings and risks.
- This device is not intended to replace the medical diagnosis of a professional doctor.
- The measurement results of this device are for reference only and cannot be directly used as a basis for clinical treatment.
- We do not recommend the use of this device if you have a pacemaker or other implantable device in your body.Please follow the doctor's advice if necessary.
- This device cannot be used with a defibrillator.
- This device cannot be used during ct or nuclear magnetic resonance (MRI) procedures.
- This equipment must not be used in a flammable environment (eg oxygen-rich environment).
- This device is not intended for use by infants weighing less than 10 kg.
- Do not swim or submerge the device in the water.Do not immerse the device in water or other liquids.
- Do not use acetone or other volatile solutions to clean the device.
- Do not strongly collide or crush the device. If the casing is

broken, stop using it.

- This device cannot be placed in a pressure vessel or gas sterilization equipment.
- Do not disassemble the device at will, otherwise it may cause machine malfunction or affect the normal operation of the device.
- Keep this device out of the reach of children or pets、pests.
- This device should not be used on people with sensitive skin or allergies.
- This equipment cannot be placed in the following environments: direct sunlight, high temperature, high humidity, close to water or fire sources, and high electromagnetic influence.
- Users should try to avoid sweating. The sweat will affect the contact between the electrodes and the skin, affecting the quality of the measurement.
- Users should inspect loosened electrodes, that can degrade performance or cause other problems
- Do not participate in violent or extensive physical activity in order to make appropriate measurements.
- The measurement results of this device cannot distinguish all diseases.If your body feels unwell, you should consult your doctor immediately, in addition to the measurement results of this device.
- Do not self-diagnose and take medication based on the measurements of this device without consulting your doctor.In particular, do not take new medications without prior permission.
- This device is not a substitute for professional heart or other organ function measurement equipment. Medical ECG measurement requires more professional and complete measurements.
- This device cannot be used to diagnose a disease directly.Please consult your doctor.

- We recommend that you record your ECG curve and the results of the measurements and provide them to your doctor if necessary.
- Waste (including the equipment itself is scrapped) is disposed of in accordance with relevant laws and regulations.
- When the ambient temperature is 20 ℃, the minimum and maximum storage temperature from the product to ready for use is 2H（the time required）.
- The patient is the expected user.
- Do not pile up the long tubing at the head of the bed,as it may wrap around the head or neck of the patient during sleep.
- Li batteries capacity will decrease after charge discharge for 300 times.
- The electrodes (Applied parts) should not contact other conductive parts including earth

2. Introduction

2.1 Intended Use

The product is intended to measure, review and store adults' ECG data at home or in healthcare environment,does not contain auto-analysis function.

2.1.1 Contraindications:

The product is not intended for use in patients with cardiac pacemakers or other implantable devices.

2.2 About ER2

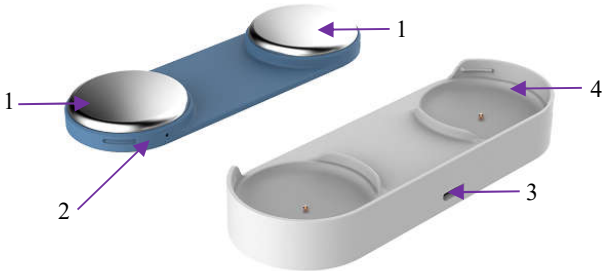

Figure 1

1. ECG electrode
   It is used to connect the body surface and receive the human body ECG signal.
2. LED indicator
   Off: The device is not activation or battery is run out,
   Green : the lead is off;
   Green and flash(According to patient heart rate rhythm):
   The device is working normally;
   Green and flash(5 seconds apart): measurement completed and the device is in normal standby mode, or when the battery is fully charged;
   Yellow : the device is charging, and it is off after being fully charged;
   Yellow and flash(5 seconds apart): the battery is low(Standby mode);
   Blue : The device is in Bluetooth connection and the device

is in normal standby mode;
Blue and flash(According to patient heart rate rhythm): The device is working normally and The device is in Bluetooth connection.

3. Charging interface
   Used to connect the charging cable.
4. Charging base
   For the product to charge.

2.3 Symbols

Symbol	Significance
	Type CF-Applied Part
	Manufacturer
	Authorized representative in the European Community
CE 0197	This product complies with the Europea Council Directive 93/42/EEC(Medical Device Directive)
	Caution , Incorrect use may cause personal injury and damages of goods. Refer to instruction manual.
IP22	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.
	Follow Instructions for Use.
	Non-ionizing radiation
SN	Serial number
	Indicate separate collection for electrical and electronic equipment (WEEE).

2.4 Product structure and composition

This product is mainly composed of ECG recorder main unit, charging base, charging cable and strap (optional).

2.5 Software information

Software name: ECG recorder software

Release version： V1.0

3. Using Instructions

3.1 Before use

⚠Warnings and Cautionary Advices

Before taking measurements, please pay attention to the following points to ensure the accuracy of the measurement data.

- Use only the cables and accessories specified in this manual.
- This device has no alarm function and therefore does not generate an audible alarm for the result of the measurement.
- Ungrounded equipment next to the patient and interference from electrosurgery can cause waveform instability.

3.2 Open box to check

Please check the box carefully before unpacking.If you find any damage, please contact the carrier or the company immediately

If the package is complete, unpack the package in the correct way and carefully remove the device and other components from the box. Check the device for any mechanical damage and

complete items.
If you have any questions, please contact us immediately.

⚠ **Warnings and Cautionary Advices**

- Please save the box and packing materials for future transportation or storage.
- When handling packaging materials, you must follow local regulations or the hospital's waste disposal system and place the packaging materials out of reach of children.
- The device may be contaminated by microorganisms during storage, transportation and use. Please confirm that the packaging is in good condition before use.
- The date of manufacture and the date of use of the product are listed on the label.

3.3 Boot

When the device is shipped from the factory, it is completely inactive by default.The device should be charged to activate the device before it is used for the first time.

3.4 Measuring process

3.4.1 Measurement methods

1）Finger measurement method:
Directly touch the ECG electrode with the thumb of both hands (R on the silk screen indicates the right hand side, and L indicates the left hand side), as shown in the following figure:

Figure 2

Wrong way of operation:

a. Shake your hands at will

b. Loose fingers during measurement

2）Strap measurement method:

Attach the main unit to the strap and then wear the strap with the main unit attached to the precordium (the indicator light is facing up) as shown below.

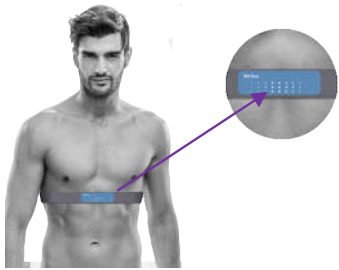

Figure 3

Precautions:

a. The ECG electrode must be in direct contact with the skin.

b. If the patient is exposed to dry skin, wipe the skin with a damp cloth before measuring.

c. When using finger measurement, make sure that your left and right hands are not in contact , otherwise the measurement results will be affected.

d. When using the strap measurement method, if necessary,

remove the hair from the electrode part, then clean the skin with water, and then apply the electrode after drying.
e. Do not speak and remain still during the measurement. Any movement will affect the measurement results.
f. Please sit when measuring possible.

3.4.2 Measuring step

1）After selecting a measurement method, the device detects that the ECG signal is automatically turned on, the signal light changes to the green and flash , the device starts to measure, and the device will emit a "drop" heartbeat sound.
2）When the measurement is over 30 seconds, the device will emit a short beep, at which point the measurement can be ended and the device will complete a 30 second-15 minutes data save.
3) When the patient continuous contact exceed 15 minutes, the device measurement time is up, the device automatically turns off, and the signal light changes to Green and flash(5 seconds apart).The device will complete a 15 minute data save.

3.5 Data view

After the measurement is completed, the data measured in the devicd can be transmitted to the mobile equipment for viewing by Bluetooth.
Steps for data export by Bluetooth:
1) Turn on the Bluetooth function of the mobile equipment to ensure that the Bluetooth function is turned on.
2) By pairing on the mobile equipment , after the pairing is successful, the indicator light will turn into a steady blue light.
3) According to the prompts of the mobile equipment, data export is implemented.
Precautions:
The device can store up to 10 part measurement data and up to 20 minutes of measurement data .In order to ensure that every data you collect is able to be viewed smoothly, please export the

data in time after each measurement is completed.

3.6 Charging

This device uses a rechargeable lithium battery.charged by connecting a laptop or a power adapter with charging cable.
Charging specific steps:
1. Place the main unit on the charging base and connect the charging base through the charging cable.As shown below.
2. Connect the charging cable to the usb port with 5v output voltage for charging.After entering the charging state, the indicator light will turn yellow and steady; when the charging is completed, the indicator light will go out.

Figure 4

⚠ Warnings and Cautionary Advices

- The device cannot be used during charging, and if choosing a third party charging adaptor (Class II), select one that complies with IEC60950 or IEC60601-1.
- Keep out of reach when charging.
- When the long-term storage is not in use, it is necessary to periodically charge the device to maintain battery performance.

4. Maintenance

⚠ Warnings and Cautionary Advices

Have the device repaired by authorized service centers only, otherwise its warranty is invalid

4.1 Warranty

The product is warranted to be free from defects in materials and workmanship within warranty period when used in accordance with the provided instructions.

4.2 Battery

When the remaining battery power is low, the indicator light will turn yellow and flash, and the device needs to be charged.

⚠ Warnings and Cautionary Advices

- The built-in rechargeable lithium-ion battery cannot be replaced.Non-professionals cannot open the enclosure and modify or replace the battery.
- Do not expose the main unit to high temperatures such as ovens,water heaters and microwave ovens.Overheat ing of the battery may explode.
- Do not contaminate or modify the battery. Doing so may cause the battery to leak, overheat, ignite or explode.
- If the battery leaks, keep your skin and eyes free from leaking liquids.If skin or eyes come into contact with leaking liquid, rinse your skin or eyes immediately and go to hospital for treatment.
- Do not throw the battery into a fire. Doing so may cause an explosion.
- When the battery exceeds the service life or no longer holds the power, you should contact the manufacturer for disposal.To dispose of the battery, follow local laws for

proper disposal.

4.3 Cleaning

ECG recorder and straps need to be cleaned regularly;clean the device per week. carefully swabbing the device with a clean, soft cloth or cotton ball with medical alcohol or water.

4.4 Recycling

Disposal of waste, residues, etc., as well as device and accessories at the end of their useful life shall not be disposed of at random and shall be in accordance with local regulations. When it is intended to discard this device, it must be sent to the appropriate facility for recycling and recycling.

4.5 Problem solving

Problem	Possible Cause	Recommended Action
The device cannot perform normal acquisition	1. The battery is low 2. Equipment damage	1. Please charge the device 2. Please contact your local agent
ECG waveform is disordered, and the clutter is large	1. Measurement method is incorrect 2. Poor contact of ECG electrode	1. Please re-measure according to the recommendations of the manual 2. Please clean the ECG electrode according to the method described in the manual.

5. accessories

Serial number	Accessory name	Quantity
1	Charging base	1
2	Charging cable	1
3	Strap (optional)	1

⚠Warnings and Cautionary Advices

- Use only the accessories specified in this manual, and using other accessories may damage the device.

7 Specifications

Classification		
Degree protection against electrical shock	Type CF	
Protection against electric shock	Internally powered equipment	
Electro-magnetic Compatibility	Group I, Class B	
Apply part	ECG electrode	
Environmental		
Item	**Operating**	**Storage**
Temperature	5 ~ 45°C	-25 ~ 70°C
Relative humidity (non-condensing)	10% ~ 95%	10% ~ 95%
Atmospheric pressure	700 ~ 1060 hPa	700 ~ 1060 hPa
Degree of dust&water resistance	IP22	
Drop test	1.0 m	
Power supply		
Type of battery	Rechargeable lithium polymer battery	
Battery specification	3.7Vdc, 90mAh	
Battery run time	48 hours (full state)	
Charging input voltage range	4.5 ~ 5.5v DC voltage	
Charging time	2 hours (to 90% power)	
ECG		
Lead type	Integrated ECG electrodes	
Lead	Lead I	
Input impendence	≥10MΩ, 10Hz	
Linearity and dynamic range	10mV (peak-to-valley)	

Common mode rejection	≥60dB
Frequency response	0.67 ~ 40 Hz
Gain error	Maximum error ±10%
Physical	
Size	92×32×8.2 mm
Packing size	172×113×59mm
weight	<50 g (with battery)
Wireless connectivity	Bluetooth connection support Built-in Bluetooth 4.0 BLE
Expected service life	5 year
Bluetooth RF	
Frequency range	2.402-2.480 GHz
	GFSK Modulation
Wireless Quality of Service (QoS)	Transmission Distance: 1.5m
	Transmission Time: ⩽ 10s for one ECG record
	Data integrity: 100%
Network topology	Point-to-Point
Band width	1Mbps
Expected service life	5 years

8 Electromagnetic compatibility

The device meets the requirements of IEC 60601-1-2.

⚠ **Warnings and Cautions**

• This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.

• The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

Guidance and manufacturer's declaration – electromagnetic emissions		
The model ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the model ECG recorder should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The model ECG recorder 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 model ECG recorder is 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	n.a.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3		

Recommended separation distances between portable and mobile RF communications equipment and the A&D unit

The model ECG recorder is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The model ECG recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The model ECG recorder 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)**		
	150kHz to 80MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80MHz to 800MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800MHz to 2.7GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.70
10	3.70	1.11	2.22
100	11.70	3.50	7.00

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.

Recommended separation distances between RF wireless communications equipment

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

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	

5240 5500 5785	0.2	0.3	9	9	frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.					

Guidance and manufacturer's declaration – electromagnetic immunity

The model ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of The model ECG recorder should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	$3V_{rms}$ 150kHz to 80MHz 10V/m 80MHz to 2.7GHz	N/A 10V/m	Portable and mobile RF communications equipment should be used no closer to any part of The model ECG recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.7GHz 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] The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c 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 whichThe model ECG recorder is used exceeds the applicable RF compliance level above, The model ECG recordershould be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating The

model ECG recorder
d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration – electromagnetic immunity			
The model ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of The model ECG recorder 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 61000-4-2	± 8 kV contact ± 2 kV，± 4 kV，± 8 kV，± 15kV air	± 8 kV contact ± 2 kV，± 4 kV，± 8 kV，± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	n.a.	n.a.
Surge IEC61000-4-5	± 1 kV line to line ±2 kV line to earth	n.a.	n.a.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T 0,5cycle At 0°,45°,90°,135°,180°,225°,270°and 315°, 0% U_T 1cycle and 70% U_T 25/30 cycles Single phase:at 0°	n.a.	n.a.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m, 50/60Hz	30A/m,50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE : U_T is the AC mains voltage prior to application of the test level.			

ER2 ECG recorder

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CE 0197

PN：255-01918-00 Version: A

Model: ER2
Revision date: July 2019

FCC Warnning:

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

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.

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.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.