ECG recorder Instructions

Model：E-B10

Nanjing Xijian Information Technology Co., Ltd.

Preface

1 Introduction of the Manual

This manual is the description on function, safety and operation of ECG recorder. The users must carefully read all chapters included in Warnings and precautions before using the ECG recorder so as to ensure the correct use of the product, so that the product could achieve the specified safety standard and performance indicators, ensuring the safety of patients and operators.

This manual will introduce the product in line with the most complete configurations, so some chapters may not applicable for your product.

Manufacturer will not bear any responsibilities for the unauthorized parts.

2 Version information

Version of the Manual: REV1.0

The version of this manual may be updated due to the change of software or technical specifications without further notice.

3 Copyright

4 Applicable object

The manual applies to all personnel. Operators of ECG recorder should understand the indispensable knowledge.

5 Product information

Product model: E-B10

Product Name: ECG recorder

Product standard number: YZB/ Su 1064-2014

Product Registration Number：Su fresh food and Drug Administration (quasi) word 2014 No. 2211254th

Production License No.：Su fresh food and Drug Administration Production Permit No. 2014-0022

Registered Address ：No.68, Shengtai Road, Jiangning Economic and Technological Development Zone, Nanjing

Production Address: Floor 3, Jinjvlong building,9 Gaohu Road, Jiangning District,Nanjing,China

6 Patent

Patents of ECG recorder product are owned by Nanjing Xijian Information Technology Co., Ltd.

7 Manufacturer responsibility

Only under the following circumstances should the manufacturer be responsible for the influences affected on equipment safety, reliability and performance.

——Assembly, supplementary, debugging, modification and repair are all carried out the

personnel authorized by the manufacturer.

——All electrical devices in the room meet relevant requirements.

——The equipment is operated under the guidance of this manual.

8 Guarantee

Nanjing Xijian Information Technology Co., Ltd. reserves the right to modify this manual and the involved products. The product parameters are subject to changes without further notice.

Any content of this manual is neither related with proposal, guarantee, promise or contract terms, nor considered as such items.

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Chapter 1 Safety

1.1 Introduction

Danger

Remind that there is a direct risk which will immediately lead to death or serious injury if it could not be avoided.

Warning

Remind that there is a potential risk which may lead to death or serious injury if it could not be avoided.

Caution

Remind that there is a potential risk or unsafe operation which may lead to slight or medium injury, damage or financial loss if it could not be avoided.

Notice

Emphasize the important precautions; provide instructions or explanation so as to use this product better.

1.2 General Safety Information

Danger

- Strangulation resulting from baby or child entanglement in monitoring cables.
- The ME EQUIPMENT labelling shall clearly indicate whether or not its use is intended for infants weighing less than 10 kg.

Warning

- The use of this product - not can be used in flammable anesthetic gas, oxygen or nitrogen oxides situations in the environment
- Do not allow any form of this product modification
- This product is not allowed to jointly make and defibrillator device
- This product is not allowed to jointly make and electrosurgical instrument
- This product does not allow common set with CT or MRI device
- No products on the high temperature, high pressure, gas steaming or liquid immersion, must be off before cleaning or disinfection
- The product display physiological waveforms, physiological parameters and prompt information for reference only to can not be directly used as the basis for the clinical treatment.
- Do not force the extrusion products, such as shell burst please stop making.
- Waste (including the product itself scrapped) were treated in accordance with the relevant laws and regulations.
- A statement indicating conductive parts of electrodes and associated connectors for

type bf or cf applied parts,including neutral electrode,should not contact other conductive parts including earth .

- The effects of degraded sensors and electrodes,or loosened electrodes, that can degrade performance or cause other problems.
- The display terminal should have Bluetooth function, otherwise unable to connect using.

Caution

- Do not use, maintain or repair the Snap ECG before reading this manual carefully.
- Keep the monitor in a dry condition and avoid water moistening and intense collision.
- The monitor use should be kept away from strong magnetic field, because it may influence the equipment test accuracy.
- If the equipment is splashed wet accidentally, please cut off the power supply immediately and wipe dry the monitor; do not use this equipment and contact with the supplier.

Notice

- The personnel under monitoring should avoid excessive and strong exercise, excessive exercise of upper limbs.
- The personnel under monitoring should avoid sweating as much as possible, because the sweat will affect the contact between electrode plate and the skin, thus affecting the monitoring quality.
- A statement indicating conductive parts of electrodes and associated connectors for type bf or cf applied parts, including neutral electrode, should not contact other conductive parts including earth
- Display equipment requirements：Bluetooth 2.0 or above；The software system for Android 4 or above； The IOS system of IOS7 or above.

Chapter 2 summarize

2.1 Intended Use

ECG recorder is applicable for monitor and record the ECG signal by medical and health care agencies and family members.

2.2 Working Principle

ECG recorder measurement of human ECG parameters are connected by the ECG electrodes .Through wireless Bluetooth transmission to a display device etc. Display apparatus having data and waveform display and storage function，At the same time with heart rate trend chart, heart rate distribution map, rhythm trend charts and abnormal rhythm distribution map display function.

2.2.1 The value of heart rate calculation method：60*1000/RR interval.

2.2.2 Arrest recognition method：RR interval >= The absolute threshold optional.

2.3 Contraindication

None

2.4 Product structure

The ECG recorder consists of a ECG recorder, ECG analyser software and ECG electrodes .

2.5 Symbol

Symbol	describe	Symbol	describe
	CF		serial number
	See instructions for use		In line with the WEEE standard
	manufacturer		production date
	Upward		dampproof
	breakable		

Table 2-1

2.6 ECG recorder Introduction

Figure 2-1

Symbol	Symbol/name	Meaning
1	Power switch	Press this button to switch the monitor between ON and OFF two modes.
2	Indicating light	ON/OFF indication; Bluetooth ON data connection indication.
3		Press this button to switch the Bluetooth between ON and OFF two modes.

Table 2-2

Chapter 3 Installation and Debugging

3.1 Unpacking

Open the packaging box and carefully take out the ECG recorder and accessories. Check whether there is damage, if damaged, please contact the seller immediately .

Notice

- **The packaging box and protective filling material should be properly kept to facilitate your transportation and storage.**
- **Comply with locally relevant regulations to handle the packaging waste.**

3.2 Software to download and install

（1）Android users in the www.mhealth365.com download the installation package.

Apple users in AppStore search handheld ECG download the installation package.

Or through the mobile phone to scan two-dimensional code on the back of the package download the installation package.

（2）After the download success tips on operation, continue to install it.

3.3 Equipment ON and OFF

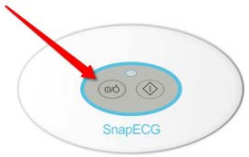
- When the machine is OFF, press the “ON/OFF button” for one second and the monitor is started (the indicating light flashes once every second);
- When the machine is ON, press the “ON/OFF button” for one second and the monitor is shutdown (the indicating light flashes slowly for three times)

3.4 Instructions for use

（1）、 The correct installation of sheet and electrode as shownwearing

（2）Open palm ECG APP, registration number (if an existing account, you can directly log).

（3）Long press dynamic ECG recorder arrow keys will be shown in the diagram below, the Bluetooth open.



（4）Go to the APP home page, click "connect" button to connect dynamic ECG recorder..

Notice

- Replace the ECG recorder, to re pairing connection.

3.5 Battery operating instructions

- ECG recorder is powered by a rechargeable battery，the battery is full before use.
- The battery can not be replaced .
- Battery charging equipment used with special charging adapter .

- When device is charging，not to position ME equipment to make it difficult to operate the disconnection device.
- Device charging matters needing attention ： The first charging line is connected to the device after will adapter to the power supply, avoid charging line short circuit, The adapter is part of a machine.

Notice

- ECG recorder is not used for a long time，battery charging 50%-80% power，stored at the temperature of 0℃ to 20℃ in a cool dry environment，and every 3 months on a single charge.
- Battery for consumables, fully charge and discharge times of the battery allowed not less than 500 times.
- Don't put the battery positive and negative connected by the shortest route, to avoid short circuit. If the battery short circuit, will lead to internal material of battery leakage or explosion.

Warning

- The battery away from the fire source, do not heat the battery, otherwise the battery may explode.
- Don't put the battery positive and negative connected by the shortest route, to avoid short circuit. If the battery short circuit, will lead to internal material of battery leakage or explosion.
- Do not use damaged, contaminated or have been leaking battery, otherwise it will explode.
- Please put the battery out of the reach of children.
- Please dispose of used batteries according to local requirements of relevant departments .

Chapter 5 Maintenance

1、Use dry clean soft cloth gently wipe or damp medical alcohol cotton ball . To avoid alcohol drops or inflow device。

2、The service life of the products for 5 years， products processing in the use of end of life should be consistent with the requirements of local laws.

Warning：

- Can not be sterilized or high pressure sterilization；
- The use of alcohol outside of the disinfectant cleaner may damage the equipment, shorten the service life or cause security risks.
- This product can not use organic solvent gasoline, thinner or similar cleaning . Do not use radiation, steam, ethylene oxide and other methods of disinfection, otherwise it will cause damage to the product .

Chapter 6 Faults and troubleshooting

fault phenomenon	cause	resolvent
Unable to boot	1、Battery power is low or no electricity 2、Equipment that may have been damaged	1、Please reboot or charging 2、Please contact the manufacturer after sale service
Unable to connect to the display terminal	1、Bluetooth is not open 2、The distance is too far 3、Wearing the wrong location	1、Turn on Bluetooth 2、The receiving equipment close to the patients 3、Adjust the wearing position
ECG showed normal	1、Wearing the wrong location 2、Equipment that may have been damaged 3 、The equipment working environment interference	1、Adjust the wearing position 2、Please contact the manufacturer after sale service 3 、Far away from the strong electromagnetic interference place

Chapter 7 packing list

order number	project	quantity
1	ECG recorder	1
2	electrocardioelectrode	10
3	instructions	1
4	certificate	1
5	warranty card	1

Appendix A Specification

Safety standards	
EN 60601-1：2006	Medical electrical equipment-Part1: General requirements for basic safety and essential performance
EN 60601-2：2007	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
Product classification	
Anti electric shock classification	common equipment of internal power
Anti electric shock degree classification	CF type application part
Protection degree against liquid	Common equipment
Electromagnetic compatibility classification	Group 1, Class B
Safety level under occasions mixed with flammable anesthetic gases, oxygen or nitric oxide	It is not applicable for use under the occasions mixed with flammable anesthetic gases, oxygen or nitric oxide
Running mode	Continuous operation
Operating environment	
Working temperature	+5℃~+40℃
Working humidity	25%～85%RH (non-condensation)
Atmospheric pressure scope	70 ～106 kPa
Transportation environment	
Temperature	-20℃～+55℃
Relative humidity	≤93% (non-condensation)
Atmospheric pressure scope	50～106Kpa
Power supply	
Internal power supply	No. 7 3.7V lithium battery
Power	0.15VA
ECG Part	
Display sensitivity	5mm/mV（X0.5）, 10mm/mV（X1）, 20mm/mV（X2）
Waveform scanning speed	12.5mm/s, 25mm/s, 50mm/s
Measurement scope	15~350bpm
Accuracy	±1bpm or ±1%, the larger one

Appendix B General Knowledge of Heart Healthy

What is the heart rate trend?

—It is the change trend of heartbeats within some time. Under normal circumstance, the heart rate per minute of the adult is 60-100 times.

What is the heart rate distribution?

— It is the proportion of normal heart rate, slightly fast heart rate, slightly slow heart rate, too fast heart rate and too slow heart rate within some time.

What is the heart rhythm trend?

— It is the heartbeat rhythm change trend within some time.

What is abnormal rhythm distribution?

— It is the proportion of arrhythmia, premature beat, atrial fibrillation and abnormal rhythm within some time.

What is premature beat?

— The normal heart beats regularly and the heart beat interval is basically the same. It is medically known as premature beat (premature beat) if sudden ahead heart beat appears.

What is atrial fibrillation?

— Atrial fibrillation is abbreviated as AF, indicating 350-360 times of irregular impulse every minute in the atrium and the extremely uncoordinated random chatter of atrial muscle fibers, thus losing the valid contraction. It mostly occurs in patients with heart diseases, such as rheumatic heart disease, coronary heart disease and hypertension.

Appendix C Product Pollution Control Identification

C.1 Environment-friendly use period (EFUP) identification

EFUP logo is established based on <Electronic Information Products Pollution Control Regulations> and <Electronic Information Products Pollution Control Identification Requirements> (SJ/T11363-2006), which is the identification applicable for electronic information products sold in China. As long as the electronic information products are used in line with safety and use instructions, since the production date, within EFUP, the toxic and harmful substances contained in the product will not have external leakage or mutation, without resulting in severe environment pollution or serious human injury or property damage. After the products are normally put into use, the products within EFUP or up to EFUP should be discarded and disposed by appropriate methods in line with the national standards. In addition, this period is different from the warranty period of quality/function.

EFUP of battery and other replaceable parts may be different with the product EFUP. As long as the products are used under the normal circumstances as stated in this manual, the “EFUP” is valid.

C.2 Toxic and harmful substance or element content table

Part name	Toxic and harmful substance or element content					
	（Pb）Lead	（Hg）Mercury	（Cd）Cadmium	（Cr(VI)）Chromium VI	（PBB）Polybrominated biphenyl	（PBDE）Polybrominated diph enyl ethers
Plastic/polymer part	○	○	○	○	○	○
Metal part	×	○	○	○	○	○
Circuit board component*	×	○	○	○	○	○
Cable and cable component	×	○	○	○	○	○
Battery	○	○	○	○	○	○
Welding flux	×	○	○	○	○	○
Battery charger	×	○	○	○	○	○

*：The circuit component includes the printed circuit board and the constituted components, such as resistors, capacitors, inductors, semiconductors and connectors.

○: indicate that the toxic and harmful substance content in all homogeneous material of this part is lower than the limit requirements as specified in SJ/T11363-2006 standard.

×: indicate that the toxic and harmful substance content in some homogeneous material of this part exceeds the limit requirements as specified in SJ/T11363-2006 standard.

Note: this table indicates that, the ECG may contain these substances.

FCC State:

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

Changes or modifications 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.

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

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