BXM-ER1
Intelligent ECG Recorder
Manual

V2.0

Before using the product, please read the content of the instruction manual carefully. Keep the manual for reference. (The pictures in this manual are for reference only)

Content

1.About safety

1.1 Precautions for use

1) Please read this manual carefully before operation.
2) Keep this manual near the equipment for easy and timely access when needed.
3) Do not use this device with MRI or CT equipment.
4) Do not use this product for testing on newborns, children and pregnant women.
5) Do not use with other devices such as pacemakers or other electrical stimulators.
6) To avoid personal injury, this equipment should not be serviced by anyone other than qualified technicians.
7) To ensure the safety of patients, please use the accessories specified by our company.
8) When the products and accessories described in this manual are about to expire, they must be disposed of in accordance with relevant regulations.
9) Do not use your mobile phone near the device as it can generate too strong a radiation field which can interfere with the functionality of the device.
10) Install or carry the device correctly to prevent the device from falling or being damaged due to collision, strong shock or other mechanical force.
11) Regularly check the instrument to ensure that there is no obvious damage to safety and test performance. It is recommend ed to check at least once a week. If the damage is evident, discontinue use of the instrument.
12) Pay attention to the positive and negative electrodes, the positive electrode should point to the heart when being worn.
13) It is not recommended to perform ECG test during strenuous exercise.

14) People weighing less than 10 kg cannot use it.
15) Do not wipe the case with abrasive paste and chemical cleaners.
16) Turn off the power when the instrument is not in use.
17) When the skin has symptoms such as damage, redness, blisters, allergies (such as skin redness and allergies due to electrode pads, replace the electrode pads, and use them after recovery).
18) The heart rate patch needs to collect the ECG signal on the surface of the human body together with the electrode pad. When the electrode pads are in poor contact (such as foreign objects on the skin or repeated peeling and sticking), the waveform is disordered and the data jumps. In order to obtain a strong ECG signal, the electrodes must be in good contact with the skin. It is recommended to clean the skin surface before use (medical sandpaper or skin scrub is best to clean the dead skin on the skin surface), and wipe the skin where the sensor will be pasted with saline.
19) Measurements determined are for informational purposes only and are not a substitute for a medical examination. Measurements can be consulted with a doctor, but should not be used to make any medical decisions.
20) The electrocardiogram issued by the recorder is for doctor's diagnosis, this product does not have the diagnosis function. It is dangerous for patients to make self-judgment and self-treatment based on the measurement results, please follow the doctor's instructions.

1.2 Symbols and description

	Applied parts of type CF		Serial number
	Separate disposal sign for waste electrical and electronic equipment.		Manufacturing date
	Manufacturer		Fragile items
	Warning		Temperature limit
	Humidity limit		Avoid sun exposure
	Avoid rain		Face up
	Follow instructions	IP22	First feature number 2: Prevent solid foreign objects: ⩾12.5mm diameter from entering Second characteristic number 2 protection against harmful water: dripping water (15º tilt)

2. Product description

2.1 Principle of operation

The professional sensors placed on the body surface are connected to the four electrodes of the device, and the potential difference between the detection points on the body surface is recorded according to the time sequence of the heart excitation. After wearing the product, it can collect human biological signals. ECG and heart rate are sent to the APP software for display or storage in real time through data processing, and the original data transmitted by the software in real time through Bluetooth displays the relevant recorded waveform data on the APP interface.

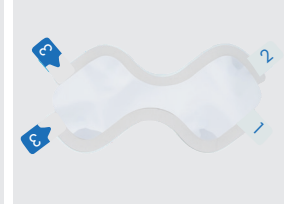
2.2 Suitable scope

Suitable for the acquisition and recording of adult single-lead ECG signals.

2.3 Composition of the product

The Bluetooth heart rate sticker is composed of the host, electrode pads, charging box and USB cable, including health management software

Bluetooth heart rate sticker



Electrode sheet

USB cable

Charging box

2.4 Environmental requirements

Normal working conditions

Temperature : 5℃～40℃
Relative humidity : 10%～95%
Atmospheric pressure : 86kPa ～106kPa

Storage and transport conditions

Temperature : -20℃～55℃
Relative humidity : 10%～95%
Atmospheric pressure : 70kPa ～106kPa

2.5 Main technical parameters

Standard sensitivity	10mm/mV , ±10%
Sampling Rate	250Hz
Internal noise	⩽25μV (peak value)
Input resistance	⩾ 50MΩ
Common mode Rejection ratio	⩾ 100dB
Frequency response	0.5Hz ~ 40Hz
Heart rate	Heart rate measurement range; 30bpm ~ 300bpm; the error should be ±2% or ±2bpm, whichever is greater
Battery	3.7V rechargeable lithium battery, 70mAh
Input power	About 5mW
Product size	Charging box size: about 145mm×60mm×30mm Heart rate patch size: about 89mm×35mm×8mm
Weight	About 137g
Charging method	Dedicated safe charging base
Bluetooth transmission	Bluetooth 4.2 transmission function
Service life	3 years

3. Instructions of operation

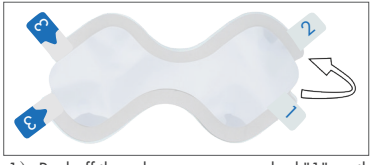
3.1 Charging the battery

1) Before using the heart rate sticker for the first time, please charge it with the charging box.
When the charging box is charging the heart rate sticker, the blue light of the charging box is always on, and the blue light of the heart rate sticker is always on, indicating that the heart rate sticker is charging. When the green light of the heart rate sticker is always on, it means that the battery of the heart rate sticker is fully charged.
2) Connect the USB adapter to charge the charging box, and connect one end to the power supply of the adapter (the adapter must bear a CCC certificate) or the USB output of the computer. At this time, the red light of the charging box flashes, indicating that charging is in progress. When the green light of the charging box is always on, it indicates that the charging box is fully charged.

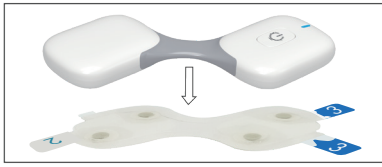
3.2 Turning on and off

1) Press and hold the power button for 2 seconds, the heart rate sticker will turn on, and the blue light will be on after turning on.
2) When the battery power is low, the yellow light of the heart rate sticker and the charging box will be on for about 30 seconds and then it will automatically turn off.
3) When the heart rate sticker is in the standby state, it will automatically turn off within about 3 minutes.

3.3 Installing the electrodes

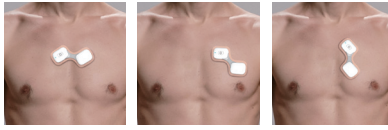


1）Peel off the release paper marked "1" on the front of the electrode sheet ;



2) Stick the heart rate to the middle of the electrode pad and press it tightly ;

3) Peel off the release paper marked "2" on the back of the electrode sheet ;

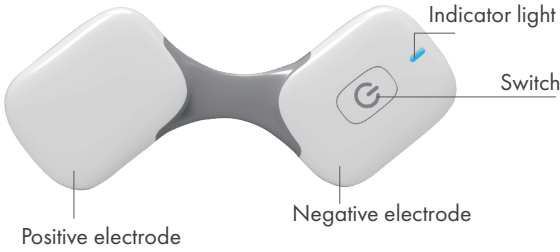


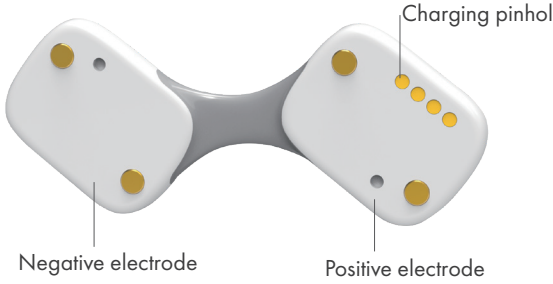
4) Stick the electrode sheet to one of the positions shown in the figure ;

5) Peel off the release paper on the front edge of the electrode sheet.

3.4 Wearing method

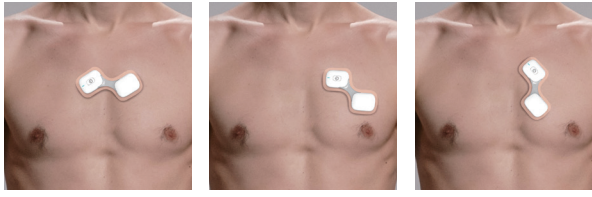
1）When wearing it, the positive pole points to the direction of the heart, the button side of the heart rate sticker is the negative pole, and the charging thimble side is the positive pole. The positive pole is pasted close to the heart, and the negative pole is pasted away from the heart. The structure description of the heart rate sticker is shown in the figure below:





After confirming the positive and negative electrodes, choose a body part with excessively uniform body tissue to ensure the stability of signal acquisition. The specific position will vary according to the size of the body, shoulder width and shoulder position. The picture below shows several basic wearing methods.

Basic diagram showing wearing methods



4. Repair and maintenance

Please keep your device and its accessories free of dust. To prevent damage to the equipment, be sure to observe the following:

1) When using the device, wipe and disinfect it with 75% alcohol, then dry it naturally or clean the product with a dry cloth. Clean at least twice a week.

2) When not in use for a long time, please store the heart rate patch in the charging box.

3) The heart rate sticker is a sophisticated electronic device. Do not attempt to disassemble or repair the interior yourself.

4) Do not use the heart rate sticker for a long time in a place that is too humid and dusty.

5) Do not throw, beat, slap, smash, knock, etc. on the heart rate sticker, and do not pull or twist it.

6) The instrument is stored in a dry, non-corrosive gas and well-ventilated room, away from direct sunlight.

7) Before using the heart rate sticker for more than a week, please charge it first and use it again

8) If the heart rate sticker is not used for a long time, it is recommended to charge it about once a month to ensure the performance of the rechargeable battery.
9) Please dispose of waste materials according to local laws.
10) Follow local ordinances and recycling instructions regarding disposal and recycling of devices and device components, including used batteries and packaging boxes.

5. Analysis of errors and repair

Serial number	Errors	Possible causes	Solutions
1	Cannot be turned on	Power of the heart rate sticker is used up	1. Put it in the charging box and fully charge ;
2	ECG waveform disorder, big waves	1. Incorrect measurement method 2. Poor contact of ECG electrodes	1. Please re-measure according to the suggestion in the manual 2. Please clean the ECG electrodes according to the method described in the manual
3	The software cannot start	Package uninstalled software system error	1. Reinstall software and upgrade in time
If your device still does not work according to the above information, or if you cannot solve the above problems, please contact the manufacturer or the nearest point of sale.			

6. After-sales services

The company will provide a one-year free warranty for this product from the date of purchase.
The company does not provide free warranty service for the errors caused by the following personal reasons of the user, as mentioned below:
(1) Failure caused by unauthorized disassembly and modification of the product;
(2) Internal failure of the fuselage caused by accidental drop during handling or use;
(3) Failures caused by improper use or lack of reasonable maintenance;
(4) Failures caused by failure to operate according to the correct knowledge in the instruction manual;
(5) Failures caused by natural disasters, such as flooding, fire, etc;
(6) Failures caused by improper repair by shops not authorized by the company.

When requesting free service, you must present a valid warranty card and proof of purchase.
When requesting warranty service, please bring this product to the point of sale for repair.
During the warranty service, if necessary, the qualified technicians identified by us can provide product circuit diagrams and repairable components information. In case of doubt, please contact the manufacturer.
Repair services outside the scope of warranty will be charged according to regulations.

7. Packing list

Smart ECG Recorder packing list			
NO.	Name	Quantity	Unit
1	Host (heart rate sticker and charging box)	1	set
2	Usb cable	1	set
3	Electrode sheet	10	sheet
4	User's guide	1	book
5	Certificate	1	piece
6	Operation manual	1	book
7	Lanyard	1	set
Remarks			

8. Electromagnetic compatibility

Guidance and manufacturer´s declaration – electro - magnetic emission – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity

1	Guidance and manufacturer´s declaration – electromagnetic emission	
2	The Smart ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of Smart ECG recorder should assure that it is used in such an environment.	
3	Emissions test	Compliance
4	RF emissions CISPR 11	Group 1
5	RF emissions CISPR 11	Class B
6	Harmonic emissions IEC 61000-3-2	Class B
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance

for all EQUIPMENT and SYSTEMS

Guidance and manufacturers declaration – electromagnetic immunity		
The Smart ECG recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart ECG recorder should assure that it is used in such an environment.		
Immunity test	EN 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15kV air
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lnes	± 2 kV for power supply lines
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	±1kV differential mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m
NOTE	UT is the a. c. mains voltage prior to application of the test level.	

Guidance and manufacturer´s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer´s declaration – electromagnetic immunity		
The Smart ECG recorder is intended for use in the electro - magnetic environment specified below. The customer or the user of the Smart ECG recorder should assure that it is used in such an environment.		
Immunity test	EN 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0, 15 MHz -80 MHz 6 V in ISM and amateur radio bands between 0, 15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0, 15 MHz -80 MHz 6 V in ISM and amateur radio bands between 0, 15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz -2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz -2,7 GHz 80 % AM at 1 kHz

Table 9 - Test specifications for enclosure port immunity to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity TEST LEVEL (V/m)
385	380 -390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation	2	0.3	28
710	704 - 787	LTE Band 13,17	Pulse modulation [b] 217 Hz	0,2	0.3	9
745						
780						
810	800 - 960	GSM 800/ 900. TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3 4, 25; UMT	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-9570	Bluetooth, WLAN, 802.11 b/g/n RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	2	0.3	9
5500						
5785						

NOTE:
If necessary to achieve the immunity test level, the distance between the transmitting antenna and the me
equipment or me system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.
a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.