

BC1

# Instruction Manual

Portable ECG Monitor



Thank you for purchasing XYZlife portable ECG monitor.

Please read this entire instruction manual. If you are using this device for the very first time, please follow the instructions and use it correctly. Please keep the instruction manual for future reference.

XYZlife does not bear legal responsibilities for any casualty or product damage caused by users' misuse.

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## Safety Conditions



This product is designed to monitor ECG (Electrocardiogram) only. Do not use for any other purpose: such as monitoring life signal or emergency. Use for self-diagnosis or self-treatment is dangerous, please always consult your doctor if you notice any change in your condition, regardless of your measurement result.

The measurement result is used for monitor purpose only.

Do not read it yourself and conduct any treatment without consult from medical professionals.

This product does not support Pacing Spikes function.

Patients with cardiac pacemaker are not recommended to use this product.


## Notification



- Do not sterilize this device in an autoclave or gas sterilizer (EO, formaldehyde, high density ozone, etc.)
- Use at temperature within +10 to +45°C, and humidity between 30 and 85%RH.
- Do not wash this device with water.
- Do not store the device in the following ambient conditions:
  - Locations subject to high temperatures and high humidity.
  - Near fires or open flames.
  - Locations exposed to strong vibration.
  - Locations exposed to strong electromagnetic fields.
  - Locations exposed to direct sunlight.
  - Wet or damp locations where water may get on the device.
  - Dusty locations.

## Attention



- Do not expose the unit to static environment.  Always avoid any static electricity from your body before handling the device.
- The chest electrode patch will be influenced by body hair. Regularly remove hair at the electrode patch contact point.
- Do not take measurement with used electrode patch.
- Do not take measurements in a moving vehicle.
- Do not disassemble, repair, or modify the device.

**WARNING !** 

- Do not use the device in ICU or operation room.
- Do not use the device in hospital or other medical institutions without the permission of physicians. This product could impact other medical devices.
- Do not use the device together with defibrillator (AED).
- Avoid flammable materials, anesthetics, drugs or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent).
- Do not attempt self-diagnosis or self-treatment based on the measurement results. Always consult your doctor. Self-diagnosis or self-treatment may lead to deterioration in your condition.
- Do not use this device on people with sensitive skin or allergic condition. With some situations, it may cause rashes, skin allergies or eczema.
- Please pay special attention to the cable of the charger to avoid the risk for tangling around the kid's neck.
- Do not strongly shock or vibrate the device. Do not drop or strike on the device.
- Avoid the areas that conduct electricity on the device to touch those of others.
- Please make sure your skin is clean and dry, avoid to use after bathing and sweating.
- Keep out of reach of children, self-care deficits or people who cannot express their consent.
- Do not use for any purpose other than obtaining an electrocardiogram.
- Do not work the device together with other test and measurement equipments to avoid risks.
- Do not take measurements where the device will be exposed to strong electromagnetic environment.
- Do not use the device on the children under age 12.

## Product Description

Single lead portable ECG monitor, is addressed as “device” below.  
The device is used to measure user’s ECG continuously.  
Recordings can be transmitted, and viewed by the collaborative App.

### The device consists of three main components:

(1) BC1 main unit.

It attaches to user’s body via electrode patch (optional) ,  
using blue tooth to keep communication with mobile devices.

(2) App: This App is used to collect, view, store, and wirelessly transfer the readings from device, it must be applied with electrode patch when taking readings.

(3) A user-supplied compatible mobile device.

### Intended use of the product:

BC1, is a portable Electrocardiograph recording device which is designed to be used in combination with an individual’s smartphone to create a portable health monitoring system. The BC1 record and store user’s physical data, wirelessly transmit such data to and display on user’s smartphone.

BC1 is intended to be use on users who require monitoring for non-life threatening arrhythmias at home.

This device has features of ECG recordings that are available to prescription users only.

This device enables a user to:

- Detect and store single-channel ECG recordings using the mobile device.
- Store user information data associated with the recording.
- Request professional clinical interpretation and analysis of your ECG recordings.
- Wirelessly transmit ECG recordings in real time to your mobile device.

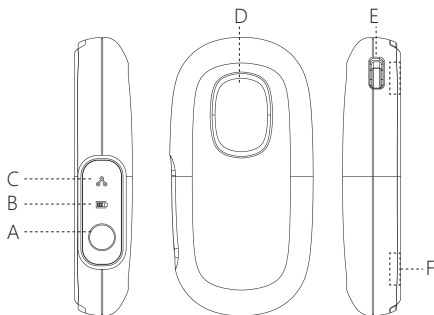
\*Determining Heart Rate: use 5 second ECG to calculate R-peak interval time, take reciprocal and then multiply 60.



### Important Notification:

Please notice that ECG recordings cannot detect all heart symptoms, and are used for physicians’ references only. Individuals who discover any change on measurement result, or diagnosed with heart disease, regardless of stable readings on electrocardiogram, should always consult doctor.

\*Photos might have slightly difference on the appearance compared to the real product.

## Component 1 / Main Unit



Main Unit	Function
A. Power Button	Press 1st time to power ON, 2nd time to power OFF
B. Battery LED 	LED light to display current battery life Green light: Full power / Flashing red light: Charging / Red light: Battery hour is less than 6 hours
C. Status LED 	LED light to show system status LED light to display current battery life Green light: Power above 60% Red light: Power less than 20%(low power) Flashing red light: in charging
D. Calling Key	Press the 1st time to call, 2nd time to cancel calling Under battery power sufficient circumstance, calling Key is working even the power is off.
E. Charging hole	For charging purpose only
F. Electroded Buckle	Buckle on electrode patch use

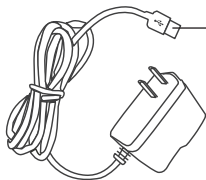
## Product Description

### Component 2 / Carry Bag



Easy carry and protection of device

### Component 3 / Charger



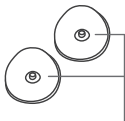
USB Connector

Model:GS2U-006-050-A  
Input: 100-240V~0.2A 60/50Hz  
Output: 5V 1200mA 6W Max  
Charger is complied with 60601-1 3.0 regulation



**\* Please use charger designated for XYZlife Patch only**

### Electrode Patch



Buckle connecting point

Device Name: Medi-Trace 200 and  
Medi-Trace 200-30 ECG Electrodes  
510(k) Number: K960968



## Initial Set Up

### 1.Charging

Take out BC1 main unit, and use USB cable start charging.

2.Download BC1 App to your mobile device (The device supports Android4.4 or more updated version, as well as iOS7.0 or more updated version.)

Please find and download Apps for XYZlife Patch on Google Play or App store).

3.Follow APP instruction to complete initial set up and Bluetooth connection.

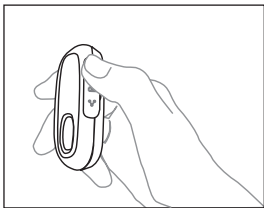
Set up the device according to selected options

### XYZlife Patch mode set up procedure (with optional electrode patch)

#### 1. Sync main unit and Bluetooth connection

-Press the power button to turn on power.  
(see the photos on the right) make sure that battery LED is green.

-Sync the device with your mobile APP  
(1st time initial setting please follow the APP instruction) and make sure the status LED is green (connect successfully). If fail to sync APP, please connect manual following the APP instruction.



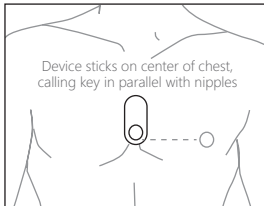
#### 2.Electrode patch and adhesive method

-At patch contact point, remove body hair or grease.

-Buckle up main unit with patch.

Remove electrode patch protect film.

Stick patch on the center of your chest (see the right photo, The electrode patch should stick vertically with calling key at downward side.



#### WARNING:

Calling key must be placed downward;  
otherwise will lead incorrect readings.

### 3. Calling Key

- Press the calling key on the front of the main unit to make warning beep sounds.
- After 30 seconds, the main unit will send calling texts to preset contact persons.

#### WARNING :

Press calling key again to stop mis-trigger (Warning beep sounds will stop)



### 4. How main unit works with APP

- Please keep main unit and mobile device within 8 meters distance
- Farer distance or additional blocks might cause data transmitting or reading issues

Note: At least 5 minutes to accumulate storage data. Data cannot be saved if removed device within first 5 minutes.



### 5. How to turn off the device

Press the power button on the side of the device; the main unit will disconnect automatically to APP on mobile device.

## Battery Life and Charge

1. The product is using Li ion rechargeable battery.
2. Use designated charger to charge the battery. Please charge fully in first time use.
3. Battery LED displays GREEN light when charging is completed.
4. The battery with full power works continuously for 8 hours.
5. Battery can be recharged at 500 times.
6. It takes around 2.5 hours to fully charge the battery.

## Caution during measurement

To obtain correct ECG readings, make sure you wear it correctly.  
Please read below notes carefully when using the device for the very first time  
Make sure to pay attention to the following notes at each use :

- Make sure the electrical buckle up firmly and correctly on patch.
- Excessive body movement could influence the measurement result: including moving, exercising, sneezing, or coughing etc.
- Electronic devices can cause interference to measurement readings.
- If you have questions about the product, consult local agent or physicians.

## Care and Maintenance

### Sound and Flashing

Sound	Message	Note
Beep/ 1 short beep	1. Confirm POWER ON/OFF	—
	2. Detect ECG signal	
Beep/ 3 long beeps	Battery power is less than 60%	—
Beep/ 5 long beep	System Error	Please refer to troubleshooting
Continuous beeps	Calling	—

Flashing Light	Message	Note
Battery LED / Red Lighting	Battery is less than 20%	
/ Red Flashing	Charging	
Status LED / Green Lighting	Connecting with APP	
/ OFF	APP disconnection	
/ Red Light	System Error	Please refer to APP Error Messages
/ Red Light Flashing	ECG signal disconnection	

### App Error Messages

Error #	Message	Cause	Solution
Error 001	Battery warning	Low battery	Please Charge
Error 002	Temp. sensor failed	Abnormal sensor signal	1. Reboot the device 2. Please contact local agent if Step 1 can not solve the problem
Error 003	G sensor failed		
Error 004	Barometer sensor failed		
Error 005	Internal storage memory error	Storage memory failed or damaged	

## Troubleshooting

Problem	Cause	Solution
Unable power ON	Battery is exhausted and voltage is too low	Please charge the device, waiting for GREEN light.
Device unable to sync with mobile	Distance between the device and mobile is too far.	Make sure the distance between device and mobile device is within 8meters. Sync APP with device manually
Abnormal Bluetooth pairing	<ol style="list-style-type: none"> <li>1. Mobile device bluetooth is OFF</li> <li>2. Mobile device bluetooth version is older than 4.0</li> <li>3. Android system is older than 4.4 or iOS older than 7.0</li> </ol>	<ol style="list-style-type: none"> <li>1. Please make sure Bluetooth is working</li> <li>2. Please make sure mobile device and Bluetooth version is updated</li> </ol>
ECG data is disappeared while using	<ol style="list-style-type: none"> <li>1. Battery is exhausted.</li> <li>2. Bluetooth connection is not working properly</li> </ol>	<ol style="list-style-type: none"> <li>1. Charging battery</li> <li>2. Make sure that mobile Bluetooth is on and sync with your device.</li> </ol>
The ECG readings appear upside down, Or unusual readings	<ol style="list-style-type: none"> <li>1. The device is positioned incorrectly</li> <li>2. ECG signal is weak</li> </ol>	<ol style="list-style-type: none"> <li>1. Make sure the electrode patch is positioned correctly</li> <li>2. Unusual readings appear: - make sure whether you use it correctly - consult your physician</li> </ol>
To many noise or interference in readings.	<p>Noise may come from interference from outside Circumstances.</p> <p>Possible interferences might be:</p> <ul style="list-style-type: none"> <li>-the device attaches body improperly</li> <li>-excessive body movement</li> <li>-EMC interference</li> </ul>	<ol style="list-style-type: none"> <li>1. Make sure electrode patch is new</li> <li>2. Do not exercise excessively while using the product</li> <li>3. Make sure electrode patch is positioned correctly</li> <li>4. Keep yourself away from high EMC Environment, such as stereo, video, or similar equipments</li> <li>5. Remove body hair and clean the skin in electrode patch contact point</li> </ol>

### Storage

1. Do not place any object on the top of the main unit, or strike it.  
This could damage it.
2. Do not wipe the device or electrode connecting point with benzene, gasoline, paint thinner, concentrated alcohol, or other solvent detergents.
3. Do not disassemble the device. Repairs should only be carried out by authorized personnel. Disassemble and repair are for authorized personnel only.
4. Do not sterilize this device in an autoclave or gas sterilizer (EO, formaldehyde, high density ozone, etc.)
5. The product does not need regular maintenance or calibration.  
If user requests the repair, please contact your local agent or our website.

## Guidance and manufacturer's declaration - electromagnetic Emissions

The BC1 ECG monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the BC1 ECG monitor should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group1	The device's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	BC1 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.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

## Recommended separation distances between portable and mobile RF communications equipment and BC1 monitor

BC1 monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the BC1 ECG monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters), the BC1 ECG monitor 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)		
	150 kHz to 80 MHz $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$	80 kHz to 800 MHz $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$	80 kHz to 2.5 GHz $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

## Guidance and manufacturer's declaration - electromagnetic immunity

The BC1 ECG monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the BC1 ECG monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of BC1 ECG monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance D = 1.2√P D = 1.2√P 80 MHz to 800 MHz D = 2.3√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 meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.  Interference may occur in the vicinity of equipment marked with the right side symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	



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.

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 BC1 ECG Monitor is used exceeds the applicable RF compliance level above, BC1 ECG Monitor should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BC1 ECG Monitor.

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



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.

Notice : The changes or modifications not expressly  
approved by the party responsible for compliance could  
void the user's authority to operate the equipment.

**IMPORTANT NOTE:** To comply with the FCC RF exposure  
compliance requirements, no change to the antenna or  
the device is permitted. Any change to the antenna or the  
device could result in the device exceeding the RF  
exposure requirements and void user's authority to  
operate the device.

**CE XXXX** product follows EC 93/42/EEC regulation

### The important message regarding EMC

With the increase use of electronic devices, such as personal computer or smart phones, any medical device might have risk of being interfered by electromagnetic from them. Any interference might lead to the medical abnormal function, causing dangerous situations.

This medical device should not interfere other devices. EN60601-1-2 regulation has been applied. The purpose for EMC regulation is to screen out insecure products. This regulation defines the bearable interference level from any medical device, and the level of output electromagnetic.

XYZlife manufactured medical device is complied with EN60601-1-2:2012 regulation. However, it is strongly recommended to follow WARNING points below:

1. Do not use the device near high volt or EMC filed.  
This may lead to device abnormal and cause some safety concern.
2. It is recommended to keep the distance of the device between them more than 8 meters
3. More EN60601-1-2:2012 documents, please go to [www.xyz-life.com](http://www.xyz-life.com) official website.

### Information on Disposal for Users of Waste Electrical & Electronic Equipment (WEEE)



This symbol on the product(s) and / or accompanying documents means that used electrical and electronic products should not be mixed with general household waste.

For proper treatment, recovery and recycling, please take this product(s) to designated collection points where it will be accepted free of charge.

User and product retail shall contact your local authority for further details of recycle this product safely. The product is not allowed to be mix disposal with other commercial waste. The product does not contain hazardous substances.

Battery disposal method shall comply with locally regulation to proceed.

## Specification

Model: BC1


ECG Channel: single channel

ECG wave measuring range : 0-2mV(  $\pm$  0.1mV error)

Heart rate range: 25 to 250 BPM (  $\pm$  5BPM)

Frequency response : 0.67Hz to 40Hz / Sample rate: 200Hz

Ingress Protection Rating: IP22

Protection type and range against electrical shock: TYPE BF 

ECG electrode is applied Part

Battery: Rechargeable Lithium ion battery

Operation Temp. : +10°C to +45°C Operation Humidity : 30% to 95%

Operation atmospheric pressure: 700-1060 mbar

Storage Temp. : -20°C to +60°C Storage Humidity: 10% to 95%

Weight: Approximate 37 g (including batteries)

Dimensions : 73mm(W) X 38mm(H) X 16mm(D)

Battery Spec. : Li-ion, 620mAh

Charger Spec. : Input: 100-240V~0.2A 60/50Hz / Output: 5V 1200mA 6W Max

Contents : BC1 main unit, Charger (comply with medical device regulatory), Carry bag, Instruction Manual, Quick guide/ Manual

Other symbols: Please carefully read the manual 

NOTE: Specifications may be changed without prior notice.

## Manufacturer









Manufacture: Kinpo Electronics, Inc.

Address: 10F, No. 99, Sec5, NanJing E. Rd, Taipei City 105, Taiwan









Website: [www.xyz-life.com](http://www.xyz-life.com)

Manufactured in Thailand

## Symbols Used for Product or Package

Symbols	Meanings
<p>Manufacturer</p> 	<p>Manufacture: Kinpo Electronics, Inc. Address: 10F, No. 99, Sec5, NanJing E. Rd, Taipei City 105, Taiwan Website: www.xyz-life.com Manufactured in Thailand</p>
<p>Lot Number</p> 	<p>Manufacturing batch / lot No.</p>
<p>Body Floating isolated applied part</p> 	<p>Protection type and range against electrical shock (Body Floating isolated applied part)</p>
<p>Date of manufacture</p> 	<p>Date of manufacture, Century year xxx month xx date xx</p>
<p>European Conformity Mark</p> 	<p>European Conformity Mark</p>
<p>WEEE – Properly Dispose of Electronic Waste</p> 	<p>Please follow WEEE regulation for properly disposal</p>
<p>Refer to instruction manual/booklet</p> 	<p>To signify that the instruction manual/booklet must be read</p>
<p>Authorized representative in the European Community</p> 	<p>XYZprinting Netherlands B.V. Address: Wagemakerstraat 7 2984 BD Ridderkerk TEL: +31 658 768 735</p>

## Symbols Used for Product or Package

Symbols	Meanings
FCC 	The device complies with Federal Communications Commission
Recycle 	Recycling Symbol
IP Code <b>IP22</b>	International protecting mark
Serial Number 	Serial Number of product
Caution 	WARNING and Cautions Please follow the instructions carefully
Temperature limit 	Transportation and storage temp. requirement
Humidity limitation 	Transportation and storage humidity requirement
Antistatic 	Warning symbol denoting a device's susceptibility to electrostatic discharge.
RF Symbol 	Radio frequency fields beyond this point may exceed the FCC, etc.

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## NOTE

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# BC1

Connecting Innovation and Health



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