User's Manual

Portable ECG MONITOR

Model： PB-20

Content

1. The Basics

Caution: Federal law restricts this device to sale by or on the order of a physician.

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.

This manual is based on the maximum configuration of **Portable ECG monitor**.

1.1 Safety

⚠ **Warnings**

- Before using the device, please ensure that you have read this manual thoroughly and fully understand corresponding precautions and risks.

- This device has been designed for practical use, but is not a substitute for a visit to the doctor.

- The data and results displayed on the device are for reference only and cannot be directly used for diagnostic interpretation or treatment.

- We recommend not to use this device if you have a pacemaker or other implanted devices. Follow the advice given by your doctor, if applicable.

- Users should always consult their physician if they notice changes in their health.

- Messages after measurement report heart rate and heart rhythm only.

- This device neither detects nor measures all heart rate, heart rhythm and heart waveform changes, especially those related to ischemic heart conditions.

- Do not use this device with a defibrillator.

- Never submerge the device in water or other liquids. Do not clean the device with acetone or other volatile solutions.

- Do not drop this device or subject it to strong impact.

- Do not place this device in pressure vessels or gas sterilization device.

- Do not dismantle the device, as this could cause damage or malfunctions or impede the operation of the device.

- This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device. Children should be supervised around the device to ensure they do not play with it.

- Do not allow the electrodes of the device to come into contact with other conductive parts (including earth).

- Do not use the device with persons with sensitive skin or allergies.

- Do not store the device in the following locations: locations in which the device is exposed to direct sunlight, high temperatures or levels of moisture, or heavy contamination; locations near to sources of water or fire; or locations that are subject to strong electromagnetic influences.

- Do not swing the device with the strip, which may result in injury.

- This device displays changes in the heart rhythm and blood oxygenation etc. which may have various different causes. These may be harmless, but may also be triggered by illnesses or diseases of differing degree of severity. Please consult a medical specialist if you believe you may have an illness or disease.

- Vital signs measurements, such as those taken with this device, cannot identify all diseases. Regardless of the measurement taken using this device, you should consult your doctor

immediately if you experience symptoms that could indicate acute disease.

- Do not self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.

- This device is not a substitute for a medical examination or your heart or other organ function, or for medical electrocardiogram recordings, which require more complex measurements.

- It is not possible to use this device to diagnose illness or diseases. This is exclusively the responsibility of your doctor.

- We recommend that you record the ECG curves and other measurements and provide them to your doctor if required.

- Do not use the product in the area of HF surgical equipment, MRI, or CT scanner, or in an oxygen rich environment.

- The battery intended to be changed only by service personnel with the use of a tool, and replacement by inadequately trained personnel may result in damage or burn.

- The patient is an intended operator.

- Do not carry out the servicing and maintenance while the product is in use.

- The patient can safely use all the functions of the product, and the patient can maintain the product by carefully reading Chapter 6.

- This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft. Turn off the Bluetooth feature in this product and remove batteries when in RF restricted areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC.

- DO NOT use this product with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the product and/ or cause an inaccurate blood pressure readings and/ or EKG recording.

- Sources of electromagnetic disturbance may affect this product (e.g. mobile telephones, microwave cookers, diathermy, lithotripsy, electrocautery, RFID, electromagnetic anti-theft systems, and metal detectors), please try to stay away from them when making measurements.

- The use of accessories and cables other than those specified or provided by manufacture could result in increased electromagnetic emission or decreased electromagnetic immunity of the product and result in improper operation.

- Interpretations made by this product are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional for clinical decision-making.

- DO NOT use this product in the presence of flammable anesthetics or drugs.

- DO NOT use this product while charging.

- Remain still while recording an ECG.

- The detectors of ECG have been developed and tested on Lead I and II recordings only.

- Do not sterilize this unit in an autoclave or gas sterilizer (EOG, formaldehyde, high density ozone, etc.)

- Do not wash this unit with water.

- This product doesn't provide on-device data backup function.

1. Introduction
1.1 Intended Use

The Portable ECG monitor is intended to be used for measuring, displaying, reviewing and storing of ECG data and Heart Rate for adult population in home or in healthcare facilities.

The device is intended to give some suggested symptoms such as regular heart beat, irregular heart beat, low HR and high HR.
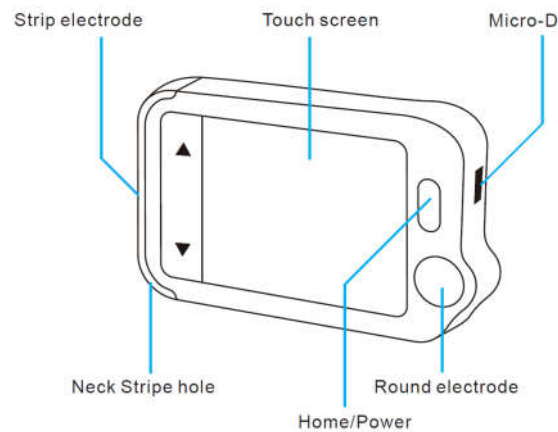
1.2 Contraindications

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

1.3 About Portable ECG monitor

product name: Portable ECG monitor

Product model: PB-20

1. Touch Screen
   Use the pad of your finger to tap or swipe on the touch screen. Do not use your fingernail or any other object to tap the screen.

2. LED indicator
   - Off: the monitor is turned off;
   - Green: the monitor is turned on, and working normally; or when the battery is fully charged;
   - Blue: the battery is being charged;
   - Red and flash: the battery is low;
3. Multi-functional micro D connector
   It connects with external ECG cable, or charging cable.
4. Home, Power On/Off
   - When the monitor is off, press this button to power it on.
   - When the monitor is on, press and hold it for 2 seconds to turn it off.
   - During operation, pressing this button will switch to Main Screen or return to upper menu.
5. Round electrode
   Use right thumb to press on it.
6. Strip electrode
   Put it to your left palm, left abdomen or left knee.
7. Neck stripe hole (neck stripe not provided)
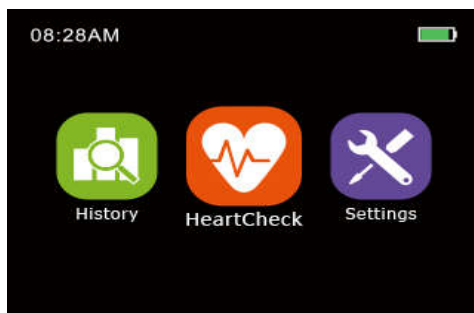8. Back electrode
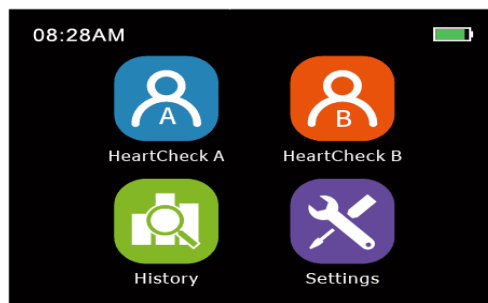   Use right index finger or middle finger to press on it.

9. ECG cable with 2 lead wires
   Connect the micro D connector side to the device and the other side to your left/right wrists or right clavicle /left lower abdomen.

1.4 Main Screen

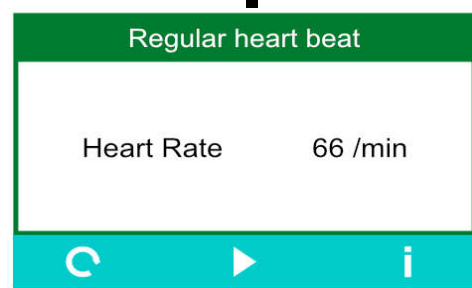The Main Screen is shown as below.
User Mode: Single

User Mode: Dual

Tapping a button in the Main Screen will start a measurement, activate a function, or open corresponding menu.

1.5 Result Screen

This device provides ECG Recorder For each measurement, a Result report will be provided after the measurement is finished. An example is shown below.

1. Measured parameters and readings
2. Buttons

- Select ↻ button to start a measurement again.
- Select ▶ button to review waveform.
- Press ℹ button to open the help information.

In the Result Screen, if there is no operation for 1 minutes, the device will automatically return to upper menu until it powers off.

1.6 Symbols

Symbol	Meaning
🧍	Application part type BF
🏭	Manufacturer
🗑	Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice".
IP22	Against ingress of solid foreign objects ≥12.5mm diameter, against dripping (15° tilted)
(MR)	MRI unsafe, presents hazards in all MR environments as device contains strongly ferromagnetic materials.
📖	Follow operating instructions
(((•)))	Non-ionizing radiation
🔋	Battery indicator

1.7 Abnormal ECG

Display content	Conditions
High HR(Fast heart rate)	More than 100/ min
Low HR(Slow heart rate)	Less than 60/ min
Irregular beat	No R-waves detected for 2 seconds and more
	R-R variation rate is more than 10% of the normal intervals
	R-R interval is less than 80% of the normal intervals
	When PVC detected
Regular beat	None of the above

2. Getting Started

2.1 Unpacking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or us. If the packing case is intact, open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage. Contact us in case of any problem.

⚠ **Warnings**

- **Save the packing case and packaging material as they can be used if the device must be reshipped.**

- **Keep the warranty card, which is useful within the period of warranty.**

- **When disposing of the packaging material, be sure to observe the applicable waste control**

regulations and keep it out of children's reach.

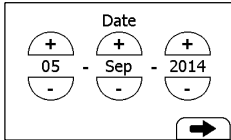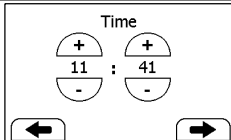- **The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact. In case of any damage, do not apply it to patients.**

2.2 Power On/Off

Press the Power On/Off button to power on the device. Press and hold Power On/Off button for 2 seconds to power off the device.

2.3 Initial Settings

The first time Portable ECG monitor is powered on, you can follow the steps below to set up your monitor.

Step	User Interface	Action
1	Date + + + 05 - Sep - 2014 - - - ➡	Tap the "+" or "-" button to change the date, month and year. Then tap ➡.
2	Time + + 11 : 41 - - ⬅ ➡	Tap the "+" or "-" button to change the time. Then tap ➡.
3	08:28AM History HeartCheck Settings	The Main Screen shows when you finish the steps as above.

3. Using the device

3.1 Prior to Use

⚠ **Warnings**

- **Use only cables, and accessories specified in this manual.**

- **The device has no alarms and will not sound if the measurement reading is too low or too high.**

Before using ECG

Before using ECG Recorder function, pay attention to the following points in order to obtain precise measurements.
- The ECG electrode must be positioned directly against the skin.
- If your skin or hands are dry, moisten them using a damp cloth before taking the measurement.
- If the ECG electrodes are dirty, remove the dirt using a soft cloth or cotton bud dampened with disinfectant alcohol.
- During the measurement, do not touch your body with the hand with which you are taking the measurement.
- Please note that there must be no skin contact between your right and left hand. Otherwise, the measurement cannot be taken correctly.
- Stay still during the measurement, do not speak and hold the device still. Movements of any kind will affect the measurements.
- If possible, take the measurement when sitting and not when standing.

⚠ **Warnings**

- **When connecting external electrodes and/or patient cables, make sure that the connectors never come into contact with other conductive parts, or with earth. In particular, make sure that all of the**

ECG electrodes are attached to the patient, to prevent them from contacting conductive parts or earth.

- If using the ECG for long-term monitoring, periodically inspect the electrode application site to ensure skin quality. If the skin quality changes, replace the electrodes or change the application site.

- Do not use this device during defibrillation.

- Interference from a non-grounded instrument near the patient and electro surgery interference can causes problems with the waveform.

⚠ **Warnings**

- **Limit finger movement as much as possible when using ECG Recorder which might result in incorrect reading or measurement result.**

- **The Portable ECG monitor is MR unsafe. Do not use this device in an MR environment as it contains strongly ferromagnetic materials. Induced current could potentially cause burns.**

3.2 ECG Recorder

About ECG Recorder

⚠ **Warnings**

- **Before using this function, please read the Section 3.1.**

Different methods of taking the ECG measurement are available on Portable ECG monitor.

The ECG recorder offers four different methods to measuring ECG. Tap the **<External>** icon to switch between two pages.
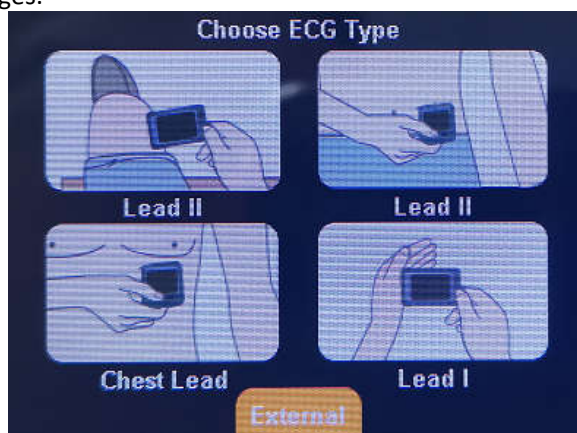
As shown above, from left to right, there are:
- ■ Method A: Lead II, right hand to left leg or right hand to left abdomen
- ■ Method B: Chest Lead , right hand to left chest（Left electrode touches left chest, 2 inch below the nipple）
- ■ Method C: Lead I, left hand to right hand

Model External require using external ECG cable and electrode, which is a bit more complicated, but offers better measurement. A message of "Note: Use ECG cable to measure for higher accuracy" will be show when chooses the method without the ECG cable. No matter which method you choose to measure ECG, please keep stable posture and stay calm during the measurement. Movements may result in interference and incorrect readings or measurement result.

Generally, it is recommended to use method A or B in most situations if the ECG waveform

amplitude is too small for better interpret.

Measuring with Cable

To start an ECG Recorder measurement without cable,
1. In the HeartCheck model, tap the **<External>** icon.
2. Choose the **<Lead I>** named method A or **<Lead II>** named method B.
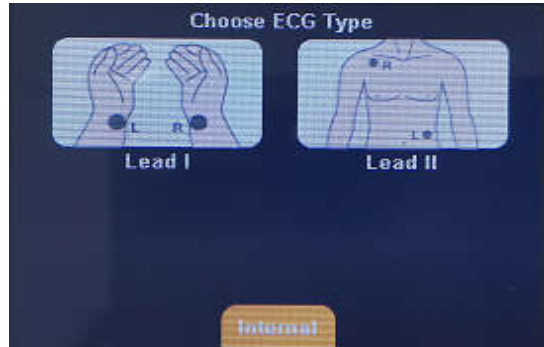
3. Follow the instructions to connect the ECG cable and place the ECG electrodes.
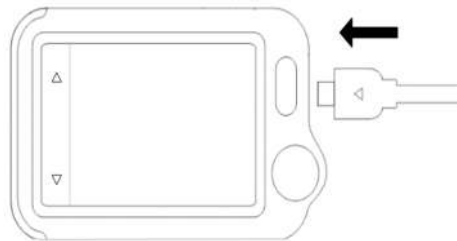
- For method A, palms facing up, place electrodes marked with L/R in the middle of left/right wrist respectively;
- For method B, place electrodes marked with R/L in the right clavicle/left lower abdomen respectively;

It is important to maintain good contact with the ECG electrodes in order to achieve an accurate ECG reading. If the device does not detect good contact between the electrodes and the skin, the warning "Touch electrodes properly" will be displayed. Do not press the device too firmly against your skin, which may result in EMG (electromyograph) interference. After you finish the above steps, hold the device stably and stay calm.

4. Once the device detects stable waveform, it will automatically start the measurement. The countdown bar moves from left to right.
5. When the bar if fully filled, the device will show the measurement result.
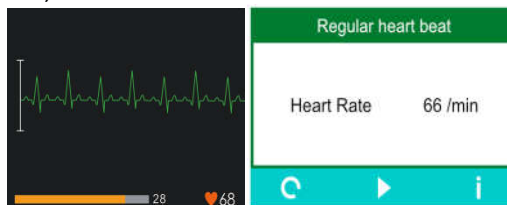
Please refer to **Section 1.7** to understand the result screen.

4. Settings

4.1 Opening Settings Menu

To open the Settings menu,
1. Press the Home button to enter the Main Screen.
2. Tap the <**Settings**> icon to open the menu as below.
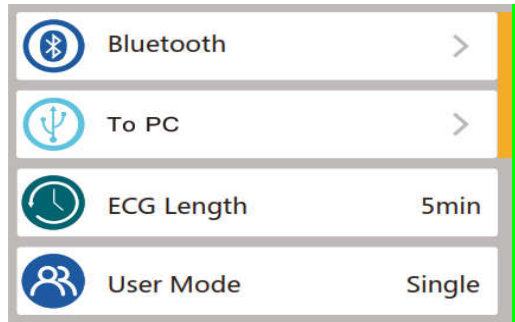
In the Settings menu, you can
- Tap ▲ and ▼ button to page up or down
- Tap home button to close the Settings menu

4.2 Turning On/Off Bluetooth

Portable ECG monitor has built-in Bluetooth wireless connectivity, which enables exporting measured records from the device to mobile devices use Bluetooth protocol.

To turn on the Bluetooth:
1. Switch on the device Bluetooth in Setting->Bluetooth.
2. Make sure the phone Bluetooth is enabled.
3. Select the product ID from the phone, then the product will be paired successfully with your phone.
4. You can export the measured data including ECG data to you phone.

Note:

- The Bluetooth technology is based on a radio link that offers fast and reliable data transmissions. The Bluetooth uses a license-free, globally available frequency range in the ISM band-intended to ensure communication compatibility worldwide.

- The pairing and transmitting distance of wireless function is 1.5 meters in the normal. If the wireless communication is delay or failure between the phone and the product, you will try to narrow the distance between the phone and the product.

- The product can pair and transmit with the phone under the wireless coexistence environment (e.g. microwaves, cell phones, routers, radios, electromagnetic anti-theft systems, and metal detectors), but other wireless product may still interface with pairing and transmission between the phone and the product under uncertain environment. If the phone and the product display inconsistent, you may need to change the environment.

4.3 Setting ECG Length

1. In the Setting menu, choose <ECG Length>.
2. Change the mode between 30s ,60s and 5min.

4.4 Changing User Mode

1. In the Settings menu, tap <User Mode>.
2. Change the mode between Single and Dual.

4.5 Changing Brightness

In the Settings menu, tap <Brightness> to change brightness

4.6 Turn on/off voice

In the Settings menu, tap the <**Voice**> to turn off voice directly. "●" means the voice is turned on.

4.7 Setting Date & Time

1. In the Settings menu, tap <**Date & Time**>.
2. Tap "+" or "-" button to change the date, then tap ➡.
3. Tap "+" or "-" button to change the time.
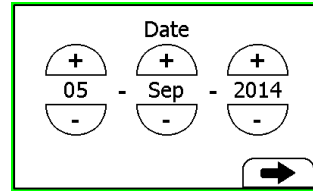
4. Tap ➡ to finish the setting.

4.8 Erase Data

1. In the Settings menu, tap the <Erase All Data>
2. Tap <Yes> to erase all data, tap <NO> to cancel option.

4.9 Factory Reset

1. In the Settings menu, tap the <Factory Reset>
2. Tap <Yes> to load default settings, tap <NO> to cancel option.

4.10 Identify Software Version

Choose <About> in the <Settings> menu to identify the software version of your device. Telling the version information when reporting a problem may help to identify and solve your problem.

5. Review ECG Recorder

Tap the <History>icon to review measurement result and waveform. In this menu, you can choose a record from the list.
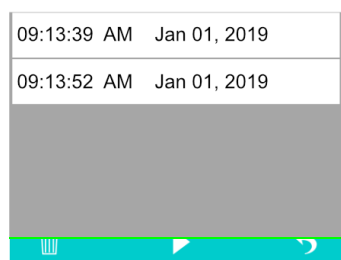
In this menu, you can,
■ Select 🗑 to delete this
■ measurement
■ Select ▶ to replay the ECG
■ waveform as shown below.

When the ECG waveform is being replayed, you can

- Select ɪĪ to change the waveform amplitude.
- Press Home button to return Daily Check list.

After the ECG waveform is replayed, it will automatically return to the previous interface.

■ Select ↺ to return to the previous interface.

Note: **the capability of storing 100 measurements(30s/one meter or 60s/one meter) or 25 measuremets(5min/one meter)**

ECG Measurement Principle

The product collects the ECG data through the potential difference of the body surface through the ECG electrode, and obtains accurate ECG data after being amplified and filtered, then displays through the screen.

6. Maintenance

⚠ Warnings

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

6.1 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. The warranty extends only to the end user. We will, at our option, repair or replace without charge the product covered by the warranty. Repair or replacement is our only responsibility and your only remedy under the warranty.

6.2 Battery

The product is designed to operate on rechargeable Lithium-ion battery. The battery is charged automatically when the monitor is connected to an adapter which can output electronic power and is approved by IEC 60601-1

On-screen battery symbols indicate the battery status as follow:

▰▰ The battery is fully charged.

▰▱ The solid portion represents the remained battery energy. If the solid portion moves from left to right, then it means that the battery is being charged.

▱ Indicates that the battery is almost depleted and need to be charged immediately. Otherwise the device will shut down automatically.

To charge the battery,

1. Connect the smaller end of the charging cable to the multi-functional connector, as shown below.

2. Connect the other end of the USB charging cable to the USB charging port.
3. Please make sure that the LED is blue
4. When the LED turns to green, it means the battery is fully charged. Then you can unplug the USB cable.

⚠ Warnings

- The product cannot be used (including measurement and review) during charging.

- When choosing a third-party USB charging device, select one that complies with IEC 60950.
- The service life of the battery will depend on the conditions of use, but on average it will support 500 charging / discharging cycles.

6.3 Cleaning

⚠ **Warnings**

- Have the device repaired by authorized service centers only, otherwise its warranty is invalid.
- Clean the device per week, carefully swabbing the device surface with a soft cloth or cotton swab with rubbing 70% alcohol.
- Do not pour alcohol directly on or into the device.

6.4 Trouble Shooting

Problem	Possible Cause	Solution
The device does not turn on.	1. The battery may be low. 2. The device might be damaged	1. Charge the battery and try again. 2. Please contact with your local distributor.
Low battery indicator is blinking	The battery is low.	Charge the battery and try again.
The ECG waveform amplitude is small	The lead you choose is not suitable for you.	Change another lead and try again.
ECG waveform drifts or disappears and "Touch electrodes properly" displayed.	1. The pressure exerted on the electrode is not stable or too much. 2. Hand or body may be moving.	1. Hold the device stably and gently. 2. Try to keep perfectly still and test again.
"System Error" occurred.	Software or hardware failure.	Restart the device and measure again. If the error persists, mark down the error number and contact with your local distributor.

6.5 Disposal

Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic's waste.

7. Accessories

⚠ **Warnings**

- Use accessories specified in this chapter. Using other accessories may cause damage to the device or not meet the claimed specifications.

Part Number	Description
540-00192-00	ECG cable with 2 lead wires, snap
540-00194-00	Charging / Data Cable
560-01701-00	Carry Case

8. Specifications

Classifications	
Degree protection against electrical shock	Type BF
Protection against electric shock	Internally powered equipment
Electro-magnetic Compatibility	Group I, Class B
Apply part	ECG electrode

Environmental		
Item	**Operating**	**Storage**
Temperature	5 to 45°C	-25 to 70°C
Relative humidity (noncondensing)	10% to 95%	10% to 95%
Barometric	700 to 1060 hPa	700 to 1060 hPa
Degree of dust & water resistance	IP22	
Drop test	1.0 m	

Physical	
Size	88×56×13 mm
Packing size	171.5*113.5*59.5mm
Weight	Less than 80 g (main unit)
Display	2.4" touch screen, color, backlit
Wireless connectivity	Built-in Bluetooth dual mode, support 4.0 BLE

Power Supply	
Battery type	Rechargeable lithium-polymer battery 580 mAh
Charge time	Less than 2 hours to 90%

ECG	
Lead type	Integrated ECG electrodes External ECG cable and electrodes
Lead set	Lead I, lead II,Chest Lead
Sampling rate	500 Hz
Sampling accuracy	16 bit
Display Gain	1.25 mm/mV, 2.5 mm/mV, 5 mm/mV 10 mm/mV,20 mm/mV
Sweep speed	25 mm/s
Frequency response	External：0.05 to 40 Hz
	Internal：0.67 to 40Hz
Input impendence	≥10MΩ, 10Hz
Linearity and dynamic range	10mV (peak-to-valley)
Common mode rejection	≥60dB
HR measurement range	30 to 250 bpm
Accuracy	±2 bpm

Bluetooth RF	
Frequency range	2.402-2.480GHz

Durable period for Pulsebit EX	
Expected service life	5 years

9. FCC Statement

FCC ID: 2ADXK-6623

1. 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.

Note: The grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications 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. his 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..

9.1Reference to Standards

IEC60601-1:2005+A1:2012
IEC60601-1-2:2014
IEC/EN60601-1-11:2015
IEC60601-2-47: 2012
FCC part 15

10. 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 Portable ECG monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the model Portable ECG monitor should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The model Portable ECG monitor 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 Portable ECG monitor 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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

The model Portable ECG monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The model Portable ECG monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The model Portable 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)		
	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
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					

					frequency of the transmitter. **Recommended separation distance**
810					
870	2	0.3	28	28	Where P is the maximum output power rating of the ransmitter in watts (W) according to the
930					
1720					transmitter manufacturer and d is
1845	2	0.3	28	28	$E = \frac{6}{d}\sqrt{P}$
1970					
2450	2	0.3	28	28	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 frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
5240					
5500					
5785	0.2	0.3	9	9	

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 Portable ECG monitor is intended for use in the electromagnetic environment specified below. The customer or the user of The model Portable ECG monitor 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 Portable ECG monitor**, 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 Portable ECG monitor is used exceeds the applicable RF compliance level above, The model Portable 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 model Portable ECG monitor
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 Portable ECG monitor is intended for use in the electromagnetic environment specified below. The customer or the user of The model Portable ECG monitor 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.			

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