

Shenzhen Kingyield Technology Co., Ltd.

Bluetooth Blood Pressure Monitor

Item No.: BPW1



Tips:

- This product is a medical device. Please strictly follow the "Instruction Manual" and "Quick Use Guide" to operate and use. Otherwise, it will cause inaccurate Blood Pressure Reading.
- Please avoid being pinched when you wear the wristband.
- Do not let any third person wear the device for the user to avoid being pinched.
- Measurement can be stopped at any time by clicking on "Cancel" on screen or pressing any button, or release the watchband when you feel uncomfortable.
- The skin may have allergic reaction to device, do not wear the device for a long time to avoid skin irritation.
- Keep out of reach of children to avoid being hurt.

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1. Before Using the Device

1.1 Device Description

Bluetooth Blood Pressure Monitor, BPW1 is a fully automatic non-invasive Blood Pressure Monitor which measures systolic and diastolic blood pressure and heart rate of adult population using the oscillometric method during inflating @ 3~8mmHg/second from about 30mmHg by inflating an airbag on the wrist.

The device is powered by a rechargeable Lithium battery.

The device has a “Measurement” button for starting the measuring and can be stopped by clicking on “Cancel” on screen or pressing any button at any time when measuring.

The device can also connect the mobile platform with an MMA (mobile medical application) as its accessory.

1.2 Intended Use

This Bluetooth Blood Pressure Monitor is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method.

The device is intended for using in only adult population, not applied to the other populations such as neonatal baby. It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing.

The wrist circumference is limited to 13.5cm - 21.5cm.

1.3 Important Safety Information and Precautions

WARNING

- Contact your physician if you suspect you have a medical issue.
 - Contact your physician for specific information about your blood pressure.
- Self-diagnosis and treatment using measured results may be dangerous. Follow the instructions of your healthcare provider.

- Not for use by children, pregnant women, or pre-eclamptic patients.
- If you suffer from arrhythmia, diabetes, blood circulation problems, or apoplexy, only use the device under a physician's care.
- Prolonged over-inflation of the monitor will result in harmful injury to the patient.
- Do not use this device over a wound, as this can cause further injury.
- Too frequent measurements can cause injury due to blood flow interference.
- This device possible cause improper result due to external interference, such as acceleration during transport or transport in general.
- Do not attempt to modify this device in any way.
- Store this device in a cool, dry place. Do not subject this device to extreme temperatures, humidity, or sunlight. This device might not meet performance specifications if stored or used outside the ranges specified in the "Specifications" section. Keep away from rain. 
- Do not immerse this device in water or clean with cleaning products, alcohol, or solvents. Carefully follow cleaning instructions provided.

- Ensure that the device is used in the environment specified in the EMC declaration in this IM, otherwise, may result in improper operation.
- Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation.
- This electrical medical equipment requires specific precautions regarding electromagnetic compatibility. It must be installed and used according to the electromagnetic information.
- Please use only USB 5V/1A or DC5V1A which complies with the standard of IEC 60601-1, which provide 2 MOPP.
- The device can be connected with the supply mains by the adapter which complies with the standard of IEC 60601-1, the adapter is regard as a part of the ME equipment, and please don't place the equipment in a place where it is difficult to disconnect the mains.
- Do not use this device where flammable gases or liquids are present.
- Never drop the device.

- Patient are the intended user, and warnings for service and maintenance when the device is in use.

When the device is in use, no repair and maintenance work, when the device is functioning normally, the patient can use it normally; stop using it when it is abnormal.

- The expected service life of the device is 3 years, and the storage period is consistent with the service life.
- Patients could not be measured continuously, and the next measurement was taken at least 2 minutes apart.
- Clean after each measurement and disinfect before use. Multiple device machine parts need to be cleaned and disinfected before the next patient for use.
- When the device, airbag, trachea, connector is damaged, do not self maintenance.
- The manufacturer may provide the circuit diagrams, component list, drawing notes, calibration rules, or other information to help maintenance personnel repair the equipment parts repaired by maintenance personnel designated by the manufacturer.
- The device shall not be used under visible conditions (such as magnetic field,

pressure, thermal combustible source, etc.) and needs to be used away from these conditions.

- The device moves from the lowest (or highest) storage temperature to the normal ambient temperature, waiting for 1 hour before use.
- The use of device should avoid the effects of the following conditions: cotton wool, dust, light (including sunlight); equipment or other interference sources that may cause interference; aging sensors that can reduce performance or cause other problems; the effects of pets, insects or children.
- The electromagnetic field may affect the product, causing the device not to be used normally, or the inaccurate measurement results. Therefore, blood pressure cannot be measured near the electromagnetic field.
- Warning and treatment for the following conditions: Do not remove the screws to prevent inhalation or swallowing of the battery.
- The skin may have allergic reaction to device, do not wear the device for a long time to avoid skin irritation.

- Do not use accessories and other removable parts; do not use other power adapters to power or charge the device to avoid damage to the device or cause danger.
- Continuous airbag pressure causing influence of blood flow interference and injury to the patient; application and pressurization of airbag on any limb undergoing vascular intervention or treatment, or arteriovenous shunt may temporarily disturb blood flow and can cause patient injury.

application and pressurization of airbag on the wrist (arm) of the mastectomy or lymph node resection; airbag pressurization may cause temporary loss of monitoring equipment on the same limb; long-term damage to the limb due to patient's blood circulation due to the operation of the photometer.

- Please read the warnings carefully before use and follow the recommendations, otherwise it may cause physical harm.
- The device is for non-medical check of blood oxygen saturation, heart rate, sport, sleeping. the data is just for your reference.
- The device is not intended for medical diagnostic or treatment use.

- When using the folding buckle needs to be adjusted to the appropriate hole position, too tight easy to pinch the wrist.
- Please avoid being pinched when you wear the wristband.
- Do not let any third person wear the device for the user to avoid being pinched.
- Measurement can be stopped at any time by clicking on "Cancel" on screen or pressing any button, or release the watchband when you feel uncomfortable.
- Keep out of reach of children to avoid being hurt.

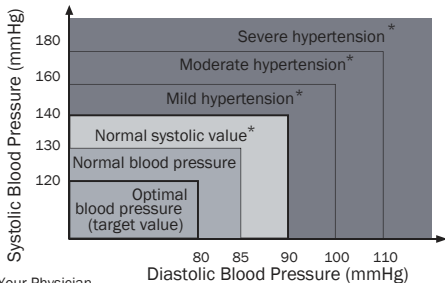
The instruction manual contains reference technical instructions.

Do not replace the wristband with the one not from the manufacturer, or may result in inaccurate measurement result.

The airbag fits wrist circumference ranging from 5.3 inches to 8.5 inches (approx. 13.5 cm to 21.5 cm), the user should confirm if the airbag fits the wrist before purchasing/using the device.

1.4 About Blood Pressure

BLOOD PRESSURE INDICATOR CHART
(World Health Organization (WHO) Blood Pressure Indicator)



*Consult Your Physician

When systolic and diastolic pressures fall into different categories, the higher pressure determines color code.

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults.

1.5 Cybersecurity informations and Recommendations

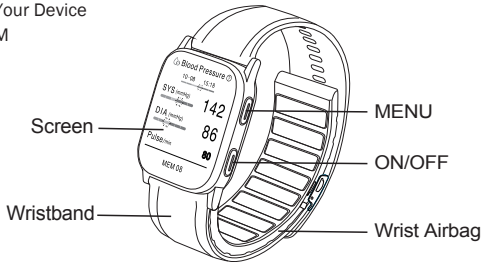
- 1.5.1. To get the mobile application to work properly, be sure to get a reliable and secure network connection.
- 1.5.2. For the correct functioning of the app, a Bluetooth connection is necessary.
- 1.5.3. Personal data are stored in a Healthcare data host (with network connection) located in China. For the security of your data, do not share your Smartphone/tablet with your app logged in. Data are transferred from your device to the Healthcare data host under a secured protocol.
- 1.5.4. The KingYield app is compatible with the following operating systems:
Android operating system: Android 7.0 or higher, iOS operating system: iOS 13.0 or higher.
- 1.5.5. Check regularly if the APP has been updated on the stores. Proceed to any product update when applicable. These updates may concern security improvement.

2 Device operation

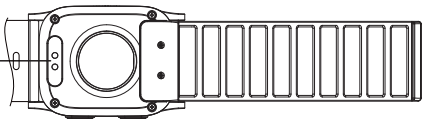
2.1 Before Using the Device

2.1.1 Know Your Device

DIAGRAM



USB magnetic
suction charging
port



Magnetic charging cable



Figure 1

2.1.2 Device Charging

Connect the blood pressure watch and the magnetic charging cable as shown in Figure 1 to charge the blood pressure watch.

The charging process as shown in Figure 2 (power increase) Display 100% means the charging finished.



Figure 2

Note: Please use only USB 5V/1A or DC5V1A power adaptor which complies with the standard of IEC 60601-1 for charging, fast charging adaptor are prohibited.

Note: It takes about 2 hours to charge to 100%; the blood pressure watch cannot be used in charging.

2.1.3 Power on and off

- a. Power on: Press and hold "On/Off" button for about 3 seconds to power on.
- b. Power off: In any interface with the screen on, press and hold "On/Off" button for about 2 seconds. The power off interface will appear. Click on "✓" icon to power off.
If you click on "✗" icon, it will return to the original interface.
- c. In the rest screen, press "Menu" button or "On/Off" button to turn on the screen.
- d. Press "Menu" button on any interface to get into the time interface.



2.1.4 Wearing and wearing adjustment

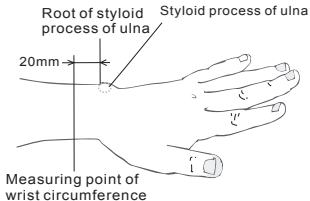
2.1.4.1 Before wearing the device

- Remove wristwatch and other jewelry.
- The device should be used on bare skin.
- Loosely roll up your sleeve to expose wrist if necessary.

a1 Measure wrist circumference

Measure wrist circumference by using a soft ruler at the measuring point which is 20mm away from root of styloid process of ulna as the figure on the right.

20.0 mm



20.0 mm



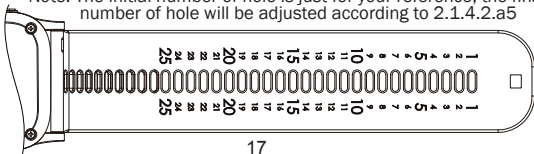
a2 Determine the initial number of hole

Determine the initial number of hole by which the wristband will be locked according to the wrist circumference measured above.

wrist circumference (CM)	13.5~13.7	13.8~14.1	14.2~14.5	14.6~14.9	15.0~15.3	15.4~15.7	15.8~16.1	16.2~16.5	16.6~16.9	17.0~17.3	17.4~17.7
Initial number of hole	22	21	20	19	18	17	16	15	14	13	12

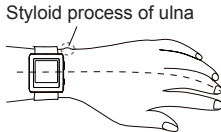
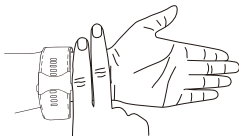
wrist circumference (CM)	17.8~18.1	18.2~18.5	18.6~18.9	19.0~19.3	19.4~19.7	19.8~20.1	20.2~20.5	20.6~20.9	21.0~21.3	21.4~21.5
Initial number of hole	11	10	9	8	7	6	5	4	3	2

Note: The initial number of hole is just for your reference, the final number of hole will be adjusted according to 2.1.4.2.a5



2.1.4.2 Wearing the device

- a1. Suggest wearing on the left hand. The skin at the wrist should remain exposed, and the sleeves of the shirt should not wrap tightly around the arms.
- a2. Ensure the width of 2-finger is maintained between the watchband and the bottom of the palm (note the position of the styloid process of ulna).



- a3. Ensure the watch body is placed on the back of the hand; the watch body cannot be located on the palm side.
- a4. Ensure the airbag extends naturally and completely between the watchband and the wrist.
- a5. Ensure the tightness of the wearing is suitable for inserting the front end of 1-2 fingers by adjusting the number of hole.



Note: The following situations will lead to inaccurate blood pressure reading!

- 1) The blood pressure watch is in the wrong position on the wrist, such as the watch body is on the palm side.
- 2) The airbag is curled between the watchband and the wrist.
- 3) The airbag is not completely between the watchband and the wrist.
- 4) The watchband is too loose or too tight.

2.2 Blood pressure measurement

2.2.1 Measurement operations

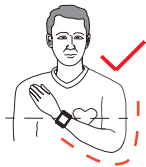
a. Before using the device

- a1. For most accurate results, measurements should be taken in the same circumstances and at the same time every day.
- a2. The device can be applied to either wrist, but preferably the left. Use the same wrist for each measurement.

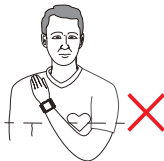
- a3. Any blood pressure recording can be affected by the position and physiological condition of the subject, as well as other factors such as background noise, stress, talking and body movement etc.
- a4. Avoid taking measurements while under stress.
- a5. Do not eat, drink alcohol, smoke, exercise, or bathe 30 minutes before using the device, as these activities may change blood pressure.
- a6. For an accurate blood pressure reading, take and record several measurements over a period of time.
- a7. Patients should have a 5-minute stop before the first measurement.
- a8. This device is used to monitor blood pressure. However, it cannot treat or prevent high blood pressure. If you suffer from high blood pressure, consult your doctor.
- a9. Correct measuring posture: Ensure the watch is at the heart height.
- a10. Relax, keep quiet and do not talk while measuring.
- a11. For continuous measurement, the interval between two measurements should be at least 2 minutes.

◆ Measuring posture while seating

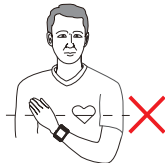
- Comfortably seated.
- Feet flat on the floor.
- Legs uncrossed.
- Back and arm supported.



Correct measuring posture



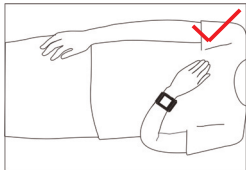
Incorrect measuring posture



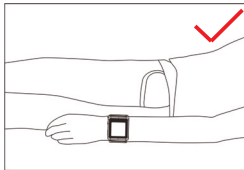
Incorrect measuring posture

Tip: Please keep your watch at the same level as your heart;
otherwise it may result in inaccurate reading!

◆ Measuring posture while lying



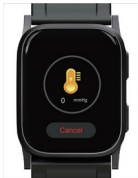
Correct measuring posture
(Do not contact the watch with other objects)



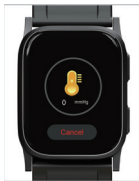
Correct measuring posture
(Do not contact the watch with other objects)

b. blood pressure measurement

- Method 1, Get into the time interface, slide left to get into the measurement interface, click on "Measurement" to start, pressure value on screen will increase and airbag will begin to inflate.



- Method 2, Get into the time interface, press "Menu" button to get into " Menu" interface, click on "Blood Pressure" to get into the measurement interface, and click on "Measurement" to start, pressure value on screen will increase and airbag will begin to inflate.



Note: Measurement can be stopped at any time by clicking on "Cancel" on screen or pressing any button, or release the watchband when you feel uncomfortable.

c. Measurement reading

When measurement is complete, the airbag deflates automatically and the systolic pressure, diastolic pressure, and pulse rate will display on screen.



“SYS” means Systolic Pressure;
“DIA” means Diastolic Pressure

Blood pressure unit:mmHg

Pulse unit: times/minute

2.3 Others

2.3.1 View MEM (Memory)

This device will store up to 80 readings. When more than 80 readings are taken, the earliest reading will be replaced.

- Get into the time interface, slide left to get into the measurement interface, and click on "📝" icon to view the average of your three most recent readings, indicated onscreen as MEM AVG(Measurement Average).



- Slide left again to see the most recent readings. Slide left repeatedly to scroll towards the earliest readings. On screen, 01 indicates the most recent readings, with higher numbers indicating earlier readings. Each slide will view a set of reading. a total of 80 sets.



Measurements
of MEM 01



Measurements
of MEM 02



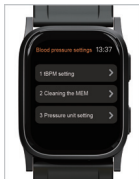
Measurements
of MEM 80

2.3.2 TBPM (Timing Blood Pressure Monitoring) setting

- Get into the time interface, press "Menu" button to get into "Menu" interface, click on "Settings" icon to get into "Settings" interface.



- Click on "Blood Pressure Settings" to get into the blood pressure setting interface; click on "1 tBPM Setting" to get into "tBPM Setting" interface, set "Start time", "End time" and "Intervals", and light the button on the right to indicate that the settings have taken effect.



- On "Blood Pressure Settings" interface, click on "2 Cleaning the MEM" to get into "Cleaning the MEM" interface, Click on "  " icon to clean MEM.

Note: When the right button is lit, the icon " " will appear in the drop-down menu interface, and measurement will automatically start at the set time point; if the right button is not lit, the icon " " will not appear, indicating that the tBPM is turned off.



2.3.3 Other functions

- a. In the time interface, slide left to get into "Add Component Interface" and click on "+" to add components such as heart rate and blood oxygen.
- b. In the time interface, press "Menu" button to get into "Menu" interface.
- c. In the time interface, slide down to get into "drop-down menu" interface.
- d. On the time interface, press and hold the interface for about 1 second to display "Change Dial" interface. Slide left or right to select the dial.

Note: The device is for non-medical check of blood oxygen saturation, heart rate, sport, sleeping. the data is just for your reference.

3 APP operation

3.1 Download

Download the "KingYield" app on your mobile or tablet and then install:



Please note this icon when downloading

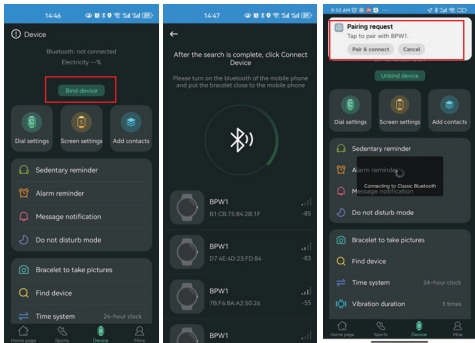
3.2 Connection

3.2.1. In "Menu" interface, click on "About" to display "Bluetooth Address".

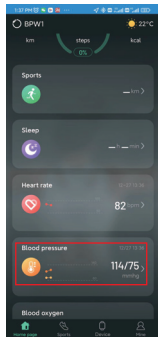


3.2.2.

After successfully logging into the APP with your mobile phone, on "Device" interface, click on "Bind Device", display the device list, click on the device on the device list against the Bluetooth address of the device, check the pairing box and click on "Pair & connect" to complete device binding.



3.2.3. After successful binding, the data will be automatically uploaded to the mobile phone; the latest blood pressure measurement readings can be viewed on "Home" interface of the mobile phone.



3.2.4. Click on "Blood Pressure" to view the user's blood pressure trend.



4 Cleaning and Maintenance

- For regular maintenance, the device only needs to be wiped gently with a soft, dry cloth while it is not being used. Never immerse the device or any components in water.
- Do not carry out repairs of any kind yourself. If a defect occurs, please contact your local authorized distributor. Use only authorized parts and accessories.
- The device's battery should be recharged periodically, even during storage since the rechargeable battery installed in the device will self-discharge, leading to an unacceptably low voltage, thus damaging the battery.

5. Troubleshooting

If you see any of these symbols displayed on screen, perform the corresponding correction:

Symbol	Cause	Correction
Warning Wearing looes	wearing is too loose	Check if the cuff is leaking. Maintenance may be needed if leaking.
		Wrap the cuff properly.
Warning Body motion interference	body motion interference	Do not move your arm and body, and keep quiet.
Warning Wearing tight	wearing is too tight	Wrap the cuff properly.
Warning Improper wearing Position	Wearing is not appropriate	Wrap the cuff properly

Bluetooth 7B:F6:8A:A2:50:26	Bluetooth address for binding	Please bind the collateral device and the device
	The battery voltage is too low	Please charge in time
 28% Charging	charging mode	In the process of charging
Warning Measurement timeout	Measurement timeout	Measure properly again

6. EMC Declaration

Guidance and Manufacturer's Declaration - Electromagnetic Immunity the device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device 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 device 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	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

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, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at level characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7GHz 9V/m, 27V/m, 28V/m 385-5785 MHz	10V/m 80MHz to 2.7GHz 9V/m, 27V/m, 28V/m 385-5785 MHz	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
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7. FCC Compliance

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.

Caution: 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.

RF Exposure Compliance

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

8. Specifications

Model No.	BPW1
Display	TFT display
Measuring Principle	Oscillometric Method
Measurable Circumference of Wrist	13.5~21.5cm(5.3"~8.5")
Electric Shock Protection	Internal power supply appliance type BF
Airbag pressure	0 to 299 mmHg
Blood pressure measurement range	30 to 230 mmHg
Pulse measurement range	40 to 180 Pulses/min
Accuracy	Pressure: ± 0.4 kPa (± 3 mmHg)
	Pulse: $\pm 5\%$ of reading
LCD Indication	Pressure: Yes
	Pulse: Yes
Inflation	Automatic by Internal Air Pump
Rapid Air Release	Automatic by Air Valve

Power Source	Built-in 3.7V Li-ion Polymer Battery which should be charged by a charger of 5V $\overline{\text{---}}$ 1A	
Charger	Magnetic suction charger	
Bluetooth	Bluetooth 5.4(data transmission), Frequency range: 2.4GHz(2402 – 2480MHz), Modulation: GFSK, EIRP for EU: < 20dBm	
Gross Weight	Approx. 65g	
Device Life	3 Years	
Operating Environment	Temperature	10~40°C (50 ~ 104°F)
	Humidity	15 ~ 90%RH(Noncondensing)
	Barometric Pressure	80~105 kPa
Transport Storage Environment	Pressure	-20~55°C (-4 ~ 131°F)
	Humidity	0 ~ 95% RH(Noncondensing)
Note: Subject to technical modification without prior notice.		

To improve performance, these specifications are subject to change without notice.

Disposal of the device, accessories and packaging shall be carried out in accordance with national and local regulations for proper handling of waste.

9. Calibration and Service

The accuracy of this Bluetooth Blood Pressure Monitor has been carefully tested and is designed for a long service life. It is generally recommended to have the device inspected and calibrated every two years to ensure correct functioning and accuracy. Please consult your authorized distributor.

10. Warranty Information

- The device is warranted to be free of manufacturing defects in workmanship and materials for a period of one year from the date listed on the purchase record, when used in accordance with the instructions provided with the device.
- This warranty does not cover damage incurred by use of the device not in accordance with the instructions, accidental damage, or being tampered with or serviced by unauthorized service agents.
- For repair of manufacturing defect under this warranty, please contact your local distributor within the period of the warranty.

This warranty covers parts and labor only under normal operations.

A transportation fee or freight fee that may be incurred will be the owner's responsibility. Any defect resulting from natural causes, e.g., flood, hurricane etc., is not within this guarantee.

- Please note warranty does not cover damage caused by, including but not

limited to: misuse or abuse; accident; the attachment of any unauthorized accessory; alteration to the product; improper installation; unauthorized repair or modification; improper use of electrical/power supply; dropped product; failure to follow required maintenance and safe-keeping; transportation damage.

This warranty specifically excludes expendables and consumables, for example batteries. All warranty claims must be directed to the distributor responsible for the sale of the device. The content of this warranty is subject to change without further notice.

The device complies with IEC 60601-1:2005+A1:2012+A 2:2020, IEC 60601-1-2:2014+A1:2020, IEC 60601-1-11:2015+A1:2020, IEC 80601-2-30:2018.

Note: To ensure accuracy, calibration by qualified technician is recommended every two years or after a repair.

Please contact your authorized distributor for details

11. Symbols Use

SYMBOLS USED IN THIS INSTRUCTION MANUAL	
 WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
 CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.
	Transport Package shall be kept away from rain.
	Refer to instruction manual/booklet
	Type BF applied part
	SERIAL NUMBER

MADE IN CHINA

VER: A00