

Shenzhen Kingyield Technology Co., Ltd.

Blood Pressure Monitor
Item No.: BPW1/2/3/5



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1. Before Using the Device

1.1 Indications For Use

This wrist blood pressure monitor is intended to be used to measure blood pressure and pulse rate from the wrist by using the oscillometric method, at home or in medical centers.

This device is intended for use on adults only and is not for use on groups such as neonatal babies, children, pregnant women, or pre-eclamptic patients.

1.2 Important Safety Information and Precautions

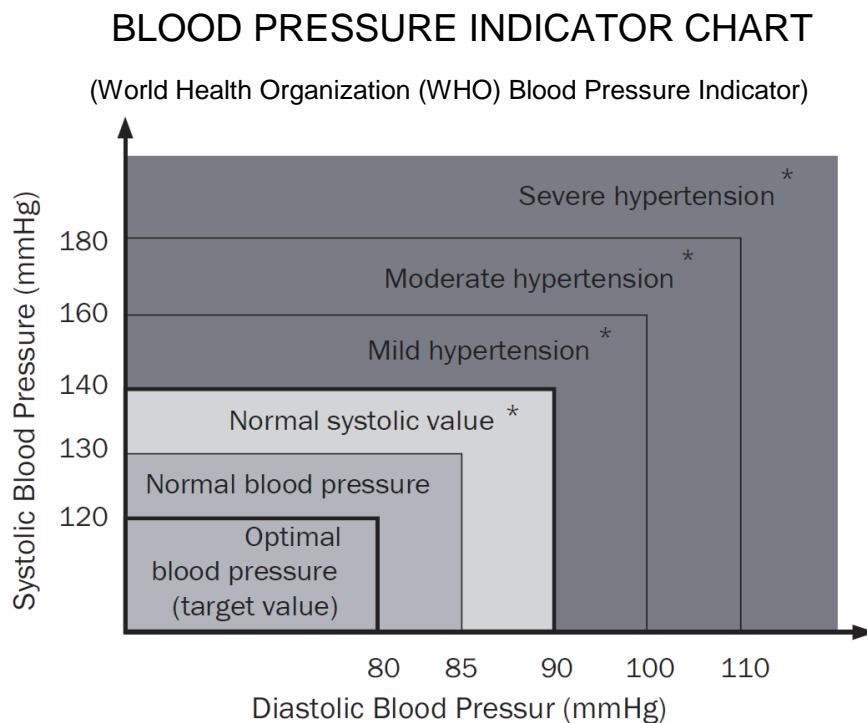
WARNING

- Contact your physician if you suspect you have a medical issue.
- 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 the device over a wound, as this can cause further injury.
- Too frequent measurements can cause injury due to blood flow interference.
- **Users should not attempt to modify the device in any way.**
- Store device in a cool, dry place. Do not subject the device to extreme temperatures, humidity, or sunlight. The device might not meet performance specifications if stored or used outside the ranges specified in the "Specifications" section.
- Do not immerse the device in water or clean with cleaning products, alcohol, or solvents. Carefully follow cleaning instructions provided.
 - **If the equipment is not available for three months or more, please use the appropriate power adapter for recharging.**
- 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.
- Do not use the device where flammable gases or liquids are present.
- **Cannot be maintained while using.**

The instruction manual contains reference technical instructions.

Prospective users are patients.

1.3 About Blood Pressure



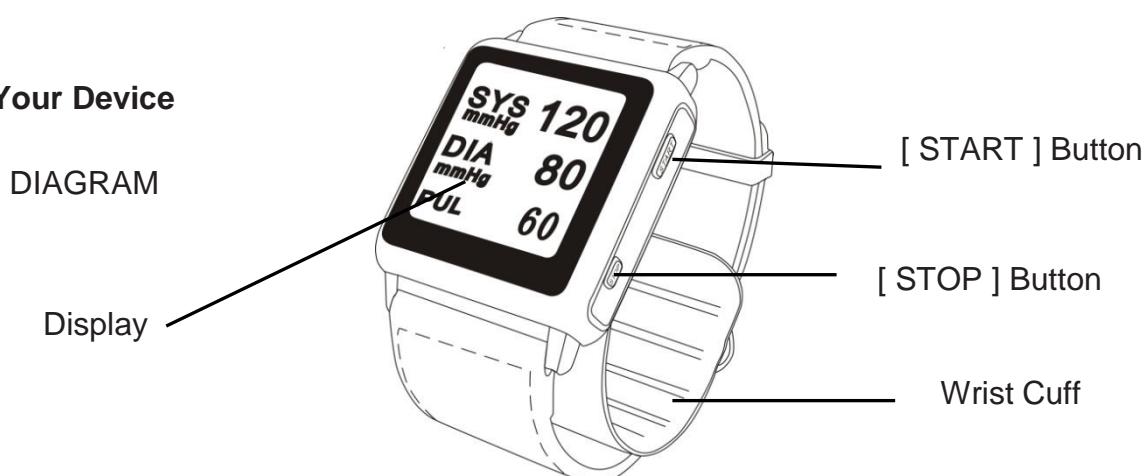
* Consult Your Physician

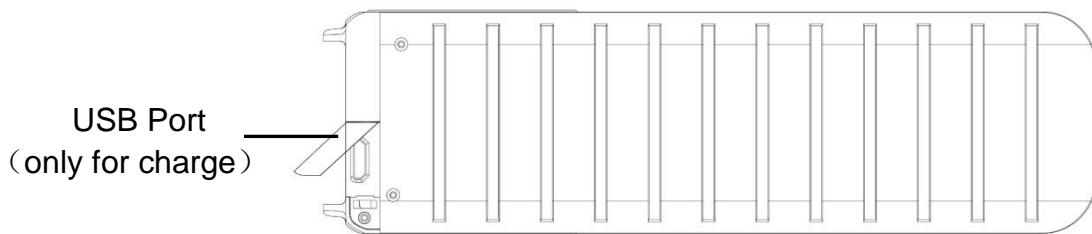
When systolic and diastolic pressure falls into different categories, the higher pressure determines color code.

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.

An irregular heartbeat rhythm is defined as a rhythm that is more than 25% slower or 25% faster from the average rhythm detected while the device is measuring the systolic blood pressure and the diastolic blood pressure. When the device detects an irregular rhythm two or more times during the measurement, the Irregular Heartbeat Symbol will be displayed with the measurement values.

2. Know Your Device





3. Instruction For Use

3.1 Before Taking a Measurement

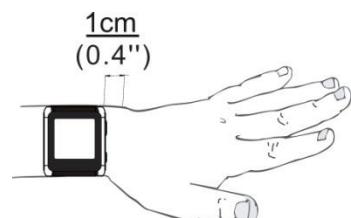
- For most accurate results, measurements should be taken in the same circumstances and at the same time every day.
- The unit can be applied to either wrist, but preferably the left. Use the same wrist for each measurement.
- Any blood pressure recording can be affected by the position and physiological condition of the subject, as well as other factors such as background noise, stress, talking and body movement etc.
- Avoid taking measurements while under stress.
- Do not eat, drink alcohol, smoke, exercise, or bathe 30 minutes before using the unit, as these activities may change blood pressure.
- For an accurate indication of true blood pressure, take and record several measurements over a period of time.
- If consecutive measurements are desired, allow two minutes between uses to allow blood to flow through the arm normally.
- 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.

3.2 Take a Measurement

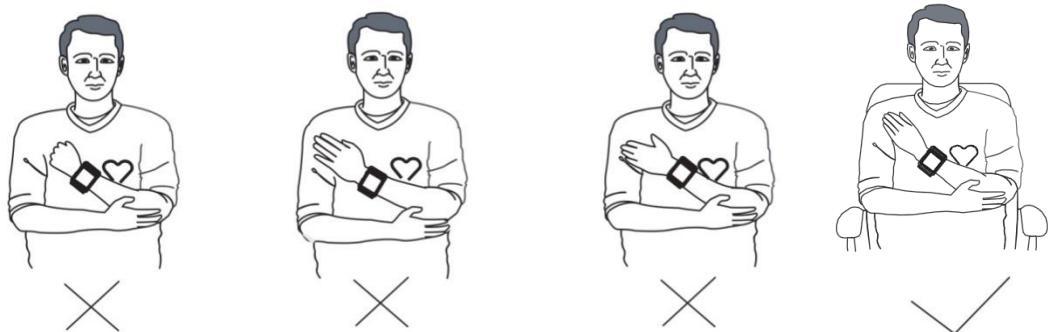
1. Ensure that the device should be used on bare skin. Remove wristwatches or other jewelry. If necessary, loosely roll up your sleeve to expose wrist.



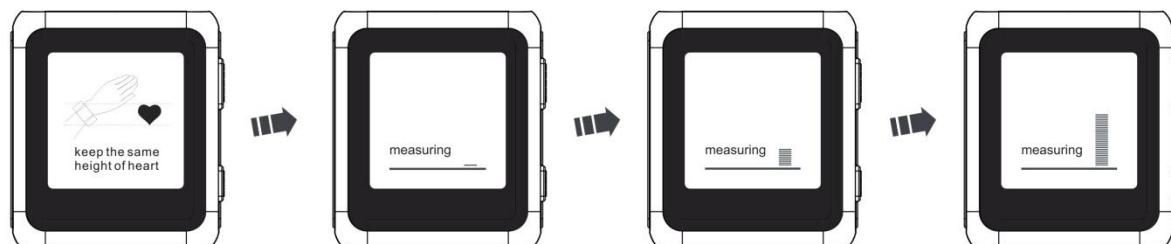
2. With screen aligned to the midline of the back of the hand, wrap and fasten the watchband with cuff around your wrist properly, not too tightly or too loose.



3. • Comfortably seated
 • Legs uncrossed
 • Feet flat on the floor
 • Back and arm supported,
 • Keep the device at the same level as your heart.
 • Relax as much as possible and not talk during the measurement.



4. While sitting upright in a chair with your feet flat on the floor, press "START". Symbols "████" on screen will increase and cuff will begin to inflate. Do not move, activate arm muscles, or talk during measurement.



5. Measurement can be stopped at any time by pressing "STOP".

6. When the unit senses a pulse, a heart symbol will flash on screen.

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

8. Turn off the device by pressing "STOP".

| | |
|-------------|-----|
| SYS mmHg | 125 |
| DIA mmHg | 72 |
| PUL | 68 |

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.

5. Troubleshooting

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

| Symbol | Cause | Correction |
|---|---------------------------------------|--|
| wearing loose | wearing inappropriate | Not with the cuff. |
| | | Wrap the cuff right too loose. |
| body motion interference | Measuring equipment turbulence | Do not move your arm and body, and keep quiet. |
| wearing tight | The ring sleeve is worn tight | Wrap the cuff right too loose. |
|  | Bluetooth connection modes | Please connect to the APP device |
|  | When the batteries power are too low. | Please charge in time. |
|  | charging mode | In the process of charging |

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 levels characteristic of a typical location in a typical commercial or hospital environment. Magnetic fields from common appliances are not expected to affect the device. |
| 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. |

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 to this device 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 to 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 to 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.

8. Specifications

| | | |
|-----------------------------------|--|--------------------------|
| Model No. | BPW1 | |
| Display | LCD 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 | |
| Measurement Range | Pressure | 0 to 299 mmHg |
| | Pulse | 40 to 180 Pulses/min |
| Accuracy | Pressure | ±3 mmHg |
| | Pulse | ±5% of reading |
| LCD Indication | Pressure | 3 Digits Display of mmHg |
| | Pulse | 3 Digits Display |
| Inflation | Automatic by Internal Pump | |
| Rapid Air Release | Automatic by Air Valve | |
| Power Source | Built-in 3.7V-210mAh Li-ion Polymer Battery which should be charged by a charger of 5V/500mA or more | |
| USB | USB 2.0 Port only for battery charge | |
| Bluetooth | Bluetooth 4.0(data transmission), Frequency range:2.4GHz(2402 – 2480MHz), Modulation: GFSK, Effective radiated power: -5dBm+/- 1dB | |
| Stand-by time | Within 2 Minutes | |
| Gross Weight | Approx. 67g | |

| | | |
|---|---------------------|----------------------------|
| Device Life | 2 Years | |
| Operating Environment | Temperature | 10~40°C (50 ~ 104 °F) |
| | Humidity | 15 ~ 90%RH (Noncondensing) |
| | Barometric Pressure | 80~106 kPa |
| Transport Storage Environment | Temperature | -20~55°C (-4 ~ 131°F) |
| | Humidity | 0 ~ 90% 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 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, or refer to www.TheDeviceSupport.com. If the equipment failure analysis, maintenance please send your authorized distributor.

10. Warranty Information

- The device is warrantied 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, IEC

60601-1-2 : 2014, IEC 60601-1-11:2015, IEC

80601-2-30:2009+A1:2013, EN 1060-3: 1995+A2:2009

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. |
|  | AUTORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY | |
|  | Transport Package shall be kept away from rain. | |
|  | Refer to instruction manual/booklet | |
|  | MANUFACTURER |  Type BF applied part |
|  | SERIAL NUMBER | |
|  | The marking of electrical and electronics devices according to Directive 2002/96/EC. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. | |
| IP22 | Moisture Protection |  0197 Bulletin board number of Germany lane |



European representative name:
 Shanghai International Holding Corp. GmbH (Europe)
 Address: Eiffestrasse 80, 20537 Hamburg Germany



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VER: A00