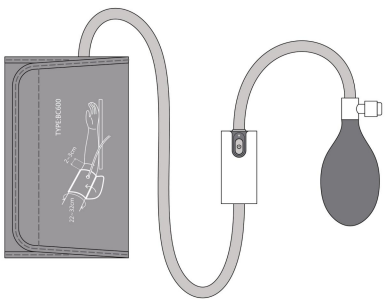
User's Manual

Ultra-Portable Smart Blood Pressure Monitor

Model BP1, BP1A



1. The Basics

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.

1.1 Safety

- Precision components are used in the construction of this device. Extremes in temperature, humidity, direct sunlight, shock or dust should be avoided.
- Clean the device and cuff with a dry, soft cloth or a cloth dampened with water and a neutral detergent. Never use alcohol, benzene, thinner or other harsh chemicals to clean the device or cuff.
- Avoid tightly folding the cuff or storing the hose tightly twisted for long periods, as such treatment may shorten the life of the components.
- The device and cuff are not water-resistant. Prevent rain, sweat and water from soiling the device and cuff.
- Do not clean or maintain the device when it in use.
- Measurements may be distorted if the device is used close to television, microwave oven, cellular telephone, X-ray or other devices with strong electrical fields.
- Used equipment, parts and battery are not treated as ordinary household waste, and

must be disposed of according to the applicable local regulations.

- When reusing the device, confirm that the device is clean.
- Do not modify the device. It may cause accidents or damage to the device.
- To measure blood pressure, the arm must be squeezed by the cuff hard enough to temporarily stop blood flow through the artery. This may cause pain, numbness or a temporary red mark to the arm. This condition will appear especially when measurement is repeated successively. Any pain, numbness, or red marks will disappear with time.
- Do not apply the cuff on an arm with another medical electrical equipment attached. The equipment may not function properly.
- People who have a severe circulatory deficit in the arm must consult a doctor before using the device, to avoid medical problems.
- Do not self-diagnose the measurement results and start treatment by yourself. Always consult your doctor for evaluation of the results and treatment.
- Do not apply the cuff on an arm with an unhealed wound.
- Do not apply the cuff on an arm receiving an intravenous drip or blood transfusion. It may cause injury or accidents.
- Do not use the device where flammable gases such as anesthetic gases are present. It may cause an explosion.
- Do not use the device in highly concentrated oxygen environments, such as a

high-pressure oxygen chamber or an oxygen tent. It may cause a fire or explosion.

- When choosing a third party charging adaptor, select one that complies with IEC 60950 or IEC 60601-1.
- Make sure the mobile APP installed in the phone with IOS software / hardware is IOS 8.0 or above, iPhone 4s / iPad 3 and models launched subsequently, or with Android software / Hardware is Android 4.0 or above, mobile phone or tablet with Bluetooth 4.0BLE.

2. Introduction

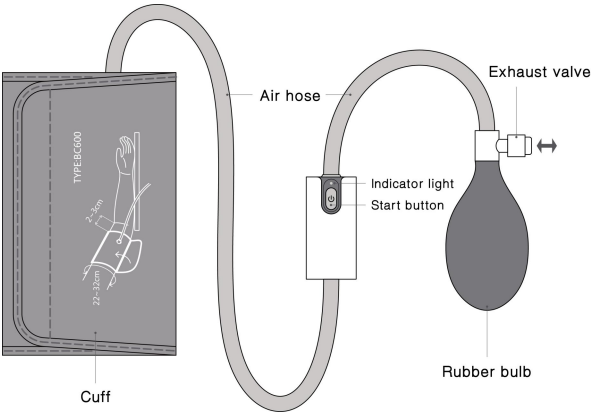
2.1 Intended Use

This product is intended for use in measuring blood pressure and pulse rate for adult patient population in home and hospital facilities.

2.2 Contraindications

- This device is contraindicated for use in ambulatory environments.
- This device is contraindicated for use on aircraft.

2.3 About the Product



2.4 Symbols

Symbol	Meaning
	Type BF-Applied Part
	Manufacturer
EC REP	European authorized representative
CE0197	CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
	Indicate separate collection for electrical and electronic equipment (WEEE).
IP22	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.

	Follow operating instructions
SN	Serial number

3. Using the Monitor

3.1 Charge the Battery

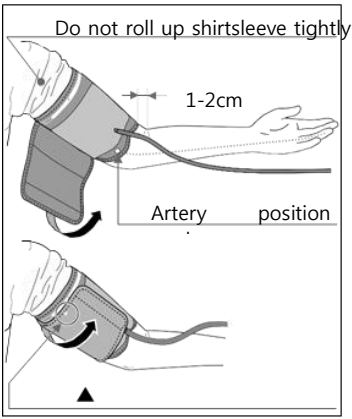
Use the USB cable to charge the monitor. Connect the USB cable to a USB charger or to the PC. A fully charge will need 2 hours. When the battery charged fully the indicator will be OFF.
The monitor works in a very low power consumption and one charge usually works for months. When the battery is low the indicator will be red flash.
On-screen battery symbols which indicate the battery status can be seen on the APP.

Note: *The device cannot be used during charging.*

3.2 LED indications

Blue blink	Powered on and Bluetooth is not connected
Blue ON	Bluetooth connected
Red blink	Low Battery
Red ON	Charging battery
Blue-Red blink	Pumped pressure is too high (above 300mmHg)

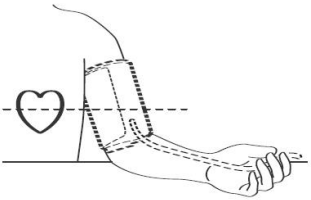
3.3 Applying the Arm Cuff



1. Wrap the cuff around the upper arm, about 1 to 2 cm above the inside of the elbow, as shown.
2. Place the cuff directly against the skin, as clothing may cause a faint pulse and result in a measurement error.
3. Constriction of the upper arm, caused by rolling up a shirtsleeve, may prevent accurate readings.
4. Confirm that the artery position mark is line up with the artery.

3.4 How to Sit Correctly

To take a measurement, you need to be relaxed and comfortably seated. Sit in a chair with your legs uncrossed and your feet flat on the floor. Place your arm on a table so the cuff is level with your heart.



3.5 Connect the Monitor to Phone

Download and install the APP **Air BP** from Apple Store or Google Play in your phone. Turn on the Bluetooth on the phone from setting menu.

1. Press the button on the monitor to power on, the indicator will be blue-flash that indicates Bluetooth ready-to-connect status.
2. Run the APP in the phone. At the first time of connect, the monitor will be listed in the screen and just choose the right monitor to start the APP. The monitor is identified by 4 numbers which should match with the 4 ending numbers of the device SN.
3. Make sure the phone sound is ON and the volume is set to loud for a clear voice instruction.

3.6 Measurement

Follow the text and voice guide on the phone to finish the measurement.

1. Pump up the cuff by squeezing the bulb at a speed guided in the APP.
2. Stop pumping after you get an instruction, hold the bulb with no squeeze or pressing, waiting

for the next instruction.

3. In some cases, if the APP judged that the pressure in the cuff is not high enough for the measurement, then an instruction of continuous pump will be issued. Just follow the instruction.
4. The monitor will automatically deflate the cuff slowly during the measurement, a typical measurement takes about 30s.
5. The blood pressure readings will appear in the phone when the measurement finished.

Note: *During the measurement, you should keep still and don't squeeze the bulb. Stop measuring when the indicator turns red. Otherwise the measurement may be effected and the blood pressure readings may be inaccurate.*

3.7 After Measurement

Press the exhaust valve to exhaust air from the cuff.
Press the button to turn off the power after the measurement. Remove the cuff.

Note: *The device has an automatic power shut-off function, which turns off the power automatically in two minute after measurement.*

Trouble Shooting

Problem	**Possible Cause**	**Recommended Action**
The monitor cannot be connected to the	The phone Bluetooth is OFF	Turn on the phone Bluetooth from the setting menu.

phone	The phone doesn't support the Bluetooth 4.0 BLE	Change to a compatible phone.
The monitor don't response to the button press.	The monitor is running in an unexpected status.	Reset the device by press and hold the button for 5s.
Cannot get blood pressure readings.	The measurement is interrupted by arm movement or unexpected bulb squeeze.	Keep arm still and don't squeeze the bulb during deflating-measure phase.
	There is an over-leakage of press	Check if the hose connection is loose.

4. Accessories

Model	Description
CU-10	Adult, arm size 22-42cm
540-00240-00	MICRO USB charge cable

Arm size: The circumference at the biceps.

5. Specifications

Classifications

EC Directive	MDD, 93/42/EEC	
	RED, 2014/53/EU	
	ROHS 2.0, 2011/65/EU	
Degree protection against electrical shock	Type BF	
Environmental		
Item	**Operating**	**Storage**
Temperature	5 to 40°C	-25 to 70°C
Relative humidity (non-condensing)	10% to 95%	10% to 95%
Barometric	700 to 1060 hPa	700 to 1060 hPa
Degree of dust & water resistance	IP22	
Physical		
Size	68mm(long)×25mm(diameter) (main unit)	
Weight	Less than 30 g (main unit)	
Cuff size	Adult cuff: 22-42cm Small adult cuff (optional): 17-22cm Adult cuff: 22-32cm	
Wireless connectivity	Built-in Bluetooth 4.0 BLE	
Power Supply		

Charge input	Micro USB, DC5V
Battery type	Rechargeable lithium-polymer battery
Battery run time	Approximately 1000 measurements
Charge time	2 hours
Blood Pressure	
Technology	Oscillometric Method
Pressure measurement range	0 – 300 mmHg
Pressure measurement accuracy	±3mmHg or±%2，whichever is greater
Pulse rate range	40 to 200 bpm
Pulse rate accuracy	±2 bpm or±%2，whichever is greater
Mobile APP	
APP function	Guide measure, display results, store and share results
IOS software / hardware	IOS 8.0 or above, iPhone 4s / iPad 3 and models launched subsequently
Android software / Hardware	Android 4.0 or above, mobile phone or tablet with Bluetooth 4.0BLE
Bluetooth RF	
Frequency range	2.402 – 2.480 GHz

Max RF power	-10 dBm

6. Electromagnetic Compatibility

The device meets the requirements of IEC 60601-1-2.

⚠ **Warnings and Cautionary Advices**

- Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The device or its components should not be used adjacent to or stacked with other equipment.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with this device even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment may affect the performance of this device.
- Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PDAs, and PCs with wireless function).

Guidance and Declaration - Electromagnetic Emissions		
The Blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission tests	**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, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Declaration - Electromagnetic Immunity			
The Blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood pressure monitor should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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.

Guidance and Declaration - Electromagnetic Immunity

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

Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 Vrms 150 kHz to 80 MHz outside ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d = 1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	Recommended separation distances: 80 MHz ~ 800 MHz: $d = 1.2\sqrt{P}$ 800MHz-2.5GHz: $d = 2.3\sqrt{P}$

			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 [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 to 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.

[a] 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 the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over frequency range 150kHz to 80MHz. For Resp field strength should be less than 1V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The Blood pressure monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Blood pressure monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.

Rated max. output power of transmitter (W)	**Separation distance according to frequency of the transmitter (m)**		
	150 kHz - 80 MHz $d=1.2\sqrt{P}$	80 MHz - 800 MHz $d=1.2\sqrt{P}$	800 MHz - 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

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.

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