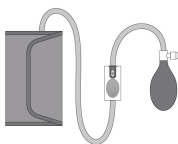


AirBP

Blood Pressure Monitor

User Manual

Model: BP1, BP1A,
BP1S, BP1SA, BP1B, BP1C



Download Phone App AirBP

iOS: App Store
Android: Google Play

Note: if you've downloaded the app before, please update it to the latest version.



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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.

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.
- Do not use in a location with moisture, or a location where water may splash on the device. This may damage the device.
- 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.
- Sources of electromagnetic disturbance may affect this device (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.
- When reusing the device, confirm that the device is clean.
- Do not disassemble or attempt to repair the monitor or components. This may cause an inaccurate reading.
- 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.



- Stop using this monitor and consult your physician if you experience skin irritation or discomfort.
- Consult your physician before using this monitor on an arm with an arterio-venous (A-V) shunt.
- Consult your physician before using this monitor if you have had a mastectomy or lymph node clearance.
- Consult your physician before using the monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- People who have a severe circulatory deficit in the arm must consult a physician before using the device, to avoid medical problems.
- Do not self-diagnose the measurement results and start treatment by yourself. Always consult your physician for evaluation of the results and treatment.
- Do not apply the cuff on the injured arm or the arm under medical treatment.
- Do not apply the cuff on an arm while on an intravenous drip or blood transfusion.
- Do not use the device with other medical electrical (ME) equipment simultaneously.
- 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 the area of HF surgical equipment, MRI, or CT scanner, or in an oxygen rich environment.
- Use only the approved arm cuff for this device. Use of other arm cuffs may result in incorrect measurement results.
- Rest for at least 5 minutes before taking the measurement.
- Remove tight-fitting or thick clothing from your arm while taking a measurement.
- Remain still and do not talk while taking a measurement.
- If the patients' arm is outside the specified circumference range (22-42cm) that may result in incorrect measurement results.
- The device is not intended for use with neonatal, pregnant, including pre-eclamptic, patients.
- Do not use the device in a moving vehicle (car, airplane).
- When choosing a third party charging adaptor, select one that complies with IEC 60950 or IEC 60601-1.



- Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.
- The patient is an intended operator.
- Do not carry out the servicing and maintenance while the device is in use.
- The patient can safely use all the functions of the device, and the patient can maintain the device by carefully reading Chapter 6.

2. Introduction

1.1 Device Description

The blood pressure monitor includes 6 models, including BP1, BP1A, BP1S, BP1SA, BP1B and BP1C.

The difference is shown as the table.

Items	BP1	BP1A	BP1S	BP1SA	BP1B	BP1C
Screen	×	×	√	√	√	√
Bluetooth	√	√	√	√	×	×
Color of Enclosure	Bright silver	Dark silver	Bright silver	Dark silver	Blue gray	Dark green

The blood pressure monitor includes six models, BP1, BP1A, BP1S, BP1SA, BP1B, and BP1C. It uses the oscillometric method to measure blood pressure, the BP1, BP1A, BP1S, BP1B support Bluetooth, while BP1B and BP1C don't. The monitor is comprised of cuff, main unit, rubber bulb, exhaust valve and air hose.



The blood pressure data is displayed, stored and reviewed including the systolic and diastolic blood pressure and pulse rate in an application which is installed in smart phone or the machine itself.

1.2 Intended Use

The subject device intended to measure the diastolic, systolic blood pressures and pulse rate for adult population in home and hospital facilities by using a non-invasive oscillometric technique with a single upper arm cuff (22-42 cm).

The device detects the appearance of irregular heart beats during measurement and gives a warning signal with readings.

1.3 Contraindications

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

1.4 Symbols

Symbol	Meaning
	Application part type BF
	Manufacturer

	Date of manufacture
SN	Serial number
	Indicates a medical device that is not to be disposed of as unsorted municipal waste.
IP22	Dustproof and waterproof level
	Follow operating instructions
	MR Unsafe – keep away from magnetic resonance imaging (MRI) equipment.
CE 0197	CE marking
	Authorized representative in the European community
FC	This product complies with the rules and regulations of the Federal Communication Commission.
	Stop pumping
	Pulse rate
	Power off
	Battery low
	Charging

3. Using the Monitor

Download App **AirBP**

iOS: App Store

Android: Google Play

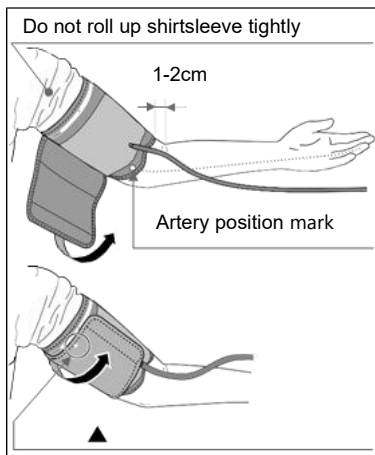
Note: if you've downloaded the app before, please update to the latest version.

3.1 Charge the Battery

Charge the monitor by using the USB cable to connect a USB charger or to the PC USB Port. A fully charge takes 2 hours.

Note: The device cannot be used during charging.

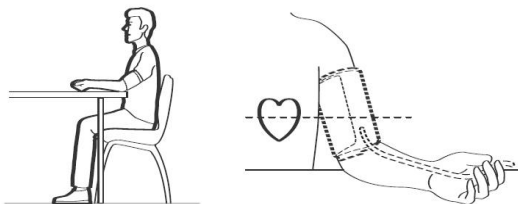
3.2 Applying the Arm Cuff



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

3.3 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. Sit with your back and arm being supported. Place your arm on a table so the cuff is level with your heart.



3.4 Single machine measurement

Press the power button to start the machine and enter the interface of waiting for measurement. Then start pumping according to the instructions. When the stop pumping sign is recognized, stop pumping and wait for the measurement result.





Measuring Result

3.5 Connect the Monitor to Phone App

1. Turn on the **Phone Bluetooth**.
2. Press the button to **power on the monitor**, the indicator will be blue-flash that indicates Bluetooth ready-to-connect status.
3. **Run the APP AirBP** on your smartphone. App will search the device. Choose your device “AirBP xxxx” in App.

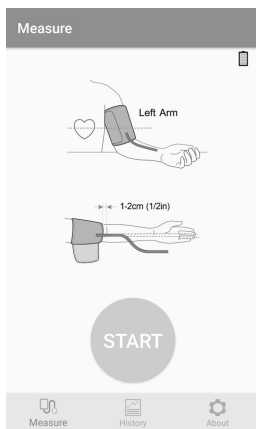
Note:

- *Keep the distance between monitor and phone within 1.5 meter.*
- *DO NOT pair in your phone settings.*
- *The APP can be downloaded in **Google Play** or **APP Store** with the name “AirBP”, which requires a smartphone.*

3.6 Measurement

Make sure your phone voice is turned on and the volume is loud enough. Follow the text and voice guide in App to measure.





In App->Measure,

- Click the “**START**” button on the App Measure Screen to start the measurement, and follow the instruction to pump up the cuff by squeezing the bulb at a speed guided in App.
- **Stop pumping** after you get the instruction, hold the bulb with no squeeze or pressing, waiting for the next instruction. In some cases, if the App judged that the pressure in the cuff is not high enough for the measurement, then an instruction of “**pump again**” will be issued.

***Note:** During the measurement, you should keep still. Otherwise the blood pressure readings may be inaccurate.*

Stop pumping when the indicator blue-red blinks (pressure is too high).



3.7 After Measurement

- The blood pressure readings will appear on the app interface when the measurement finished. You need to manually press exhaust valve to **deflate the cuff**. If you forget to deflate manually after measurement, the monitor will automatically deflate the cuff slowly, and it takes less than 30s for finishing the whole automatic deflation.
- On result page, you can add the user name or ID (help you manage multiple users data), add note, share the results or delete it.
- If the monitor detects the irregular heartbeat, and the corresponding symbol will display below to the PR value.



Note: The device turns off automatically in two minute if no working.

3.8 Review the history

- In App History, you can check the history list. You can select a specific ID or All.

History			
		All	
10:20 14-11-2018	Un-named		
Jerry	Jack	9	68
10:19 14-11-2018	Jason	1	66
10:18 14-11-2018	Jerry		
Jerry		102/61	63
15:32 13-11-2018	Jason		
Jason		102/62	60
15:29 13-11-2018	Jason		
Jason		106/64	62
15:28 13-11-2018	Jason		
Jason		109/60	62
16:58 01-11-2018	Jack		
Jack		108/74	62
16:56 01-11-2018	Jack		
Jack		106/66	55
Measure History About			



3.9 Trouble Shooting

Problem	Possible Cause	Recommended Action
The monitor cannot be connected to the phone	The phone Bluetooth is OFF	Turn on the phone Bluetooth from the setting menu.
	The phone doesn't support the Bluetooth 4.0 BLE	Change to a compatible phone.
The monitor doesn'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		
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	
Wireless connectivity	Built-in Bluetooth 4.0 BLE	
Power Supply		
Charge input	Micro USB, DC5V	
Battery type	Rechargeable lithium-polymer battery 3.7Vdc, 130mAh	
Charge time	2 hours	
Blood Pressure		
Technology	Oscillometric Method	
Measuring Range	0 – 299 mmHg	
DIA Range	40-150 mmHg	
SYS Range	60- 230 mmHg	
Pressure measurement accuracy	±3mmHg	
Pulse rate range	40 to 200 bpm	
Pulse rate accuracy	±2 bpm	



Mobile APP	
APP function	Guide measure, display results, store and share results
IOS software / hardware	IOS 12.0, iPhone launched subsequently
Android software / Hardware	Android 6.0 or above, mobile phone with Bluetooth 4.0BLE
Bluetooth RF	
Frequency range	2.402 – 2.480 GHz
Durable period for Monitor	
Expected service life	2 years

6. Maintenance and Cleaning

6.1 Maintenance

To protect your device from damage,

- Store the device and the components in a clean, safe location.
- Do not wash the device and any components or immerse them in water.
- Do not disassemble or attempt to repair the device or components.
- Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.
- The cuff contains a sensitive air-tight bubble. Handle this carefully and avoid all types of straining through twisting or buckling.
- Clean the device with a soft, dry cloth. Do not use petrol, thinners or similar solvent. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff must not be washed!
- Do not drop the instrument or treat it roughly in any



way. Avoid strong vibrations.

- Never open the device! Otherwise the manufacturer calibration becomes invalid!

6.2 Cleaning

- Clean the device with a soft, dry cloth with 70% alcohol.
- Do not use petrol, thinners or similar solvent.
- Clean the cuff carefully with cloth soaked 70% alcohol.
- The cuff must not be washed!
- Clean on the monitor and the arm cuff, and then let it air dry.

6.3 Disposal



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

7. FCC Statement

BP1、BP1A FCC ID: 2ADXX-8611

BP1S、BP1SA FCC ID: 2ADXX-8612

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.*

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

***Note:** Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.*

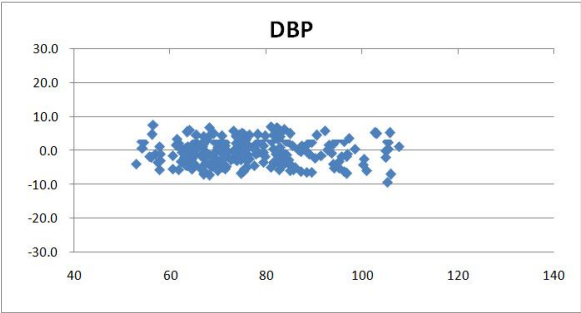
RF Exposure

The monitor complies with FCC radiation exposure limits set forth for an uncontrolled environment.



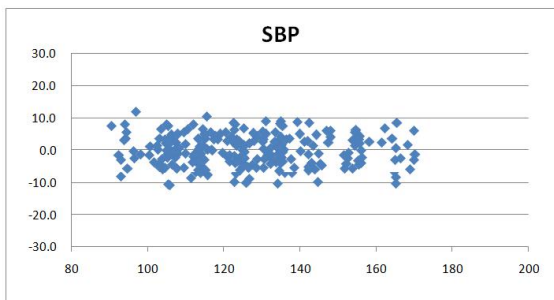
8. Reference to Standards

IEC60601-1:2005+A1:2012
IEC60601-1-2:2014
IEC/EN60601-1-11:2015
IEC80601-2-30:2009+A1:2013
ISO81060-2:2013
FCC part 15



Plot of DBP difference between the paired blood pressure determinations against the reference diastolic measurement





Plot of SBP difference between the paired blood pressure determinations against the reference systolic measurement

The Bland-Altman Plots originated from clinical test, which data was gathered from adult healthy volunteers in a controlled study.

The clinical test applies for the BP1S device with one cuff size, comparing with Mercury sphygmomanometer.

The result met the criteria specified in ISO 81060-2:2013; In addition, there were no reported adverse effects during these investigations.



9. 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).

EMC table information is listed on our website:

https://api.viatomtech.com.cn/documents/2017/emc_en.pdf

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Version: C

Date: Aug, 2020



Shenzhen Viatom Technology Co., Ltd.

4E, Building 3, Tingwei Industrial Park, No.6 Liufang Road,
Block 67, Xin'an Street, Baoan District, Shenzhen, 518101,
Guangdong, China
www.viatomtech.com



WellKang Ltd

The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

