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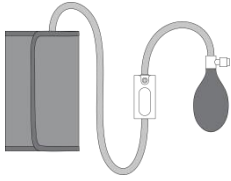
Powered by Viatom Technology

# AirBP 2

## Blood Pressure Monitor



# User Manual

## Contents

## 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, 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.
- 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.

- 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 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.
- 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.

## 2. Introduction

### 2.1 Device Description

The blood pressure monitor includes two models, BP1 and BP1A. It uses the oscillometric method to measure blood pressure with Bluetooth technology. The monitor is comprised of a cuff, a main unit, a rubber hand-pump, an exhaust valve and an air hose. The blood pressure data is displayed, stored and reviewed including the systolic and diastolic blood pressure, as well as pulse rate in an application which is installed on a smart phone.

## 2.2 Intended Use

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

## 2.3 Contraindications

- The use of this device is prohibited in ambulatory environments.
- The use of this device is prohibited on aircraft.

## 2.4 Symbols

| Symbol | Description |
|---|---|
|  | Manufacturer |
|  | Date of manufacture |
|  | Indicates a medical device that is not to be disposed of as unsorted municipal waste. |
|  | Follow Instructions for Use. |
|  | Type BF Applied Part |
|   | MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials. |
| **IP22** | Resistant to liquid ingress |
| CE 0197 | CE marking |

| | |
|---|---|
| EC REP | Authorized representative in the European community |
| UK CA | UKCA marking |
| UK REP | Authorized Representative in the United Kingdom |
| FC | This product complies with the rules and regulations of the Federal Communication Commission. |

## 3. Using the Monitor

Download the App **AirBP**

iOS: App Store

Android: Google Play

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

### 3.1 Charging the Battery

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

When the battery is low the screen of the monitor will show "▭".

In the App, you can check the battery level.

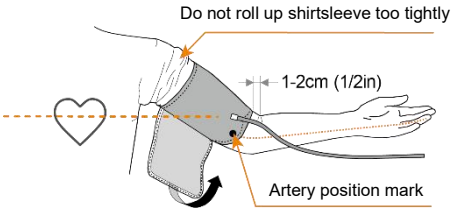
***Note:*** *The device cannot be used while charging.*

### 3.2 Beep indications

| | |
|---|---|
| two short beeps | Stop pumping |

| | |
|---|---|
| One long beep | End of measurement |
| Three short beeps | Pump pressure is too high (above 300mmHg) |

### 3.3 Applying the Arm Cuff

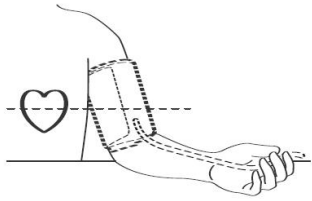



Wrap the cuff around the upper arm, about 1 to 2cm above the inside of the elbow, as shown.

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



### 3.5 Connect to the App

1. Turn on the **Phone's Bluetooth**.
2. Press the button to **power on the monitor**.
3. **Open the Air BP APP** on your smartphone. The App will search for the device. Choose your device "AirBP xxxx" in the App.

***Note:***

- *Keep the monitor and the phone within 1.5 meters of each other.*
- *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 speakers are turned on and the volume is loud enough. Follow the text and voice guide in the App to use.

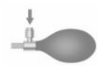
**In App->Measure**,

- Follow the instructions to inflate the cuff by squeezing the pump at the rate indicated in the App.
- **Stop pumping** according to instructions of the App, hold the pump without squeezing it, and wait for the further instructions. In some cases, if the App senses that the pressure in the cuff is not high enough for use, then the user will be instructed to "**pump again**".

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

*Stop pumping when the screen of the monitor show "Out of Rang" and beep 3 short beeps (pressure is too high).*

### 3.7 After the Test



- The blood pressure readings will appear on the App interface when the test has finished. You need to manually press the exhaust valve to **deflate the cuff**. If you forget to deflate the cuff manually after use, the monitor will automatically deflate the cuff, which takes less than 30s for full automatic deflation.
- On the results page, you can add user names and ID's to help you manage multiple users data, add notes, share results or delete them.
- If the monitor detects an irregular heartbeat, then the corresponding symbol will display below the PR value.

***Note:*** *The device will turn off automatically after two minutes if not working.*

### 3.8 Reviewing the History

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


### 3.9 Measurement without App

After you have learned how to use the App for measurement. You can also perform measurement without connecting to the app when you do not need to store data.

1. Refer to section 3.3 and 3.4 to wear the cuff.

2. Inflate the cuff by squeezing the pump at the similar rate you have learned in the App.

3. **Stop pumping** when the monitor beep twice, hold the pump without squeezing it, and wait for the further instructions. In some cases, if the monitor senses that the pressure in the cuff is not high enough for use, then the user will be instructed to "**Pump**" again.

4. **After the test.** The blood pressure readings will appear on the screen of the monitor when the test has finished. You need to manually press the exhaust valve to **deflate the cuff**.

***Note:***

- *If you want to start a new measurement, you can short press the power button of the monitor or pump.*
- *When the monitor is not connected to App for measurement, the results will not be saved.*

### 3.10 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 in the settings menu. |
| | The phone doesn't support the Bluetooth 4.0 BLE | Change to a compatible phone. |
| The monitor doesn't respond when pressing the button. | The monitor is running in an unexpected status. | Reset the device by pressing and holding the button for 5s. |
| Cannot get blood pressure readings. | The measurement is interrupted by arm movement or unexpected bulb squeezing during use | Keep the arm still and don't squeeze the bulb during deflation. |
| | There is pressure leakage. | Check the hose connection to see if it is loose. |

## 4. Accessories

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

Arm size: The circumference at the biceps.

## 5. Specifications

| **Classifications** | | |
|---|---|---|
| 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** | | |
| Charger input | Micro USB, DC 5V | |
| Battery type | Rechargeable lithium-polymer battery | |
| Estimated charging time | Approximately 2 hours | |

| | |
|---|---|
| **Blood Pressure** | |
| Technology | Oscillometric method |
| Cuff pressure Range | 0 – 300 mmHg |
| Pressure measurement accuracy | ±3mmHg |
| Pulse rate range | 40 to 200 bpm |
| Pulse rate accuracy | ±2 bpm |
| **Mobile APP** | |
| APP function | Guided measurement, display results, store and share results |
| iOS software / hardware | iOS 12.0, iPhone |
| Android software / Hardware | Android 6.0 or above, mobile phone with Bluetooth 4.0BLE |
| **Bluetooth RF** | |
| Frequency range | 2.402 – 2.480 GHz |
| Max RF power | -10 dBm |
| **Durable period for Monitor** | |
| Expected service life | 5 years |

## 6. Maintenance

### 6.1 Maintenance

To protect your monitor from damage, store the monitor and the components in a clean, safe location.
Caution: DO NOT disassemble or attempt to repair this
monitor or other components. This may cause inaccurate blood pressure readings.

### 6.2 Cleaning

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to clean your monitor and the arm cuff and then wipe them with a dry cloth.
- When electrodes are dirty, use a soft cloth or cotton swab moistened with an alcohol-based sanitizer to clean the electrodes.
- Do not use gasoline, thinners, or similar solvents to clean your monitor and arm cuff or other components.

### 6.3 Storage

Keep your monitor and other components in the storage case when not in use.

- Store your monitor and other components in a clean, safe location.
- Do not store your monitor and other components in locations exposed to extreme temperatures, humidity, direct sunlight, dust, or corrosive vapors, such as bleach.

### 6.4 Disposal

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

## 7. Electromagnetic Compatibility

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

## ⚠ Warnings and Tips

- Using accessories other than those specified in this manual may result in increased electromagnetic emissions or decreased electromagnetic immunity for the device.
- 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 CISPR requirements.
- When the inputted signal is below the minimum amplitude provided in the technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment may affect device performance.
- 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 device 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 device is intended for use in the electromagnetic environment specified below. The customer or the user of the Health 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<br>± 8 kV air | ± 6 kV contact<br>± 8 kV air | Floors should be wood, concrete<br>or ceramic tile. If floors are<br>covered with synthetic material,<br>the relative humidity should be at<br>least 30 %. |
| Electrical fast transient/burst<br>IEC 61000-4-4 | ± 2 kV for power<br>supply lines<br>± 1 kV for input/output | ± 2 kV for power<br>supply lines<br>± 1 kV for | Mains power quality should be that of a typical commercial or |

| | | | |
|---|---|---|---|
| | lines | input/output lines | hospital environment. |
| Surge<br>IEC 61000-4-5 | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | |
| Voltage dips, short<br>Interruptions and Voltage variations on power supply input lines<br>IEC 61000-4-11 | <5 % UT<br>(>95 % dip in UT)<br>for 0.5 cycle<br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><5 % UT<br>(>95 % dip in UT)<br>for 5 s | <5 % UT<br>(>95 % dip in UT)<br>for 0.5 cycle<br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><5 % UT<br>(>95 % dip in UT)<br>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<br>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 device is intended for use in the specified electromagnetic environment. The customer or the user of the Health Monitor should assure that it is used in such an environment as described below.

| **Immunity test** | **IEC60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
|---|---|---|---|
| Conduced RF<br>IEC61000-4-6 | 3 Vrms<br>150 kHz to<br>80 MHz<br>outside ISM bands | 3 Vrms<br>150 kHz to<br>80 MHz<br>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.<br>Recommended separation distances: $d = 1.2\sqrt{P}$ |
| Radiated RF<br>IEC61000-4-3 | 3 V/m<br>80 MHz to<br>2.5 GHz | 3 V/m 80 MHz to<br>2.5 GHz | Recommended separation distances:<br>80 MHz～800 MHz:<br>$d = 1.2\sqrt{P}$<br>800MHz-2.5GHz:<br>$d = 2.3\sqrt{P}$<br>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).<br>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].<br>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 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Health 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.

# 8. Declaration of conformity.

## 8.1 Directive 2014/53/EU

DECLARATION OF CONFORMITY

Directive 2014/53/EU

On The Radio Equipment Directive

Name and address of the manufacturer: **Shenzhen Viatom Technology Co., Ltd.**
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**No.6 Liufang Road, Block 67, Xin'an Street,**
**Baoan District, 518101 Shenzhen, P.R.China**

We declare under our sole responsibility that

the medical device: **Blood Pressure Monitor**
**Model:BP1, BP1A**

is in conformity with essential requirements of:

**Council Directive 2014/53/EU on Radio Equipment Directive(RED)**

| Essential Requirements | | Test Standards |
|---|---|---|
| Art 3.1(a) | Health | EN 50663:2017<br>EN 62479:2010 |
| Art 3.1(a) | Safety | EN 60601-1-2:2015, EN 60601-1-11:2015(Clause12)<br>EN60601-1:2006+A12:2014, ANSI/AAMI ES 60601-1:2005/(R)2012 and<br>A1:2012,C1:2009/(R)2012 and A2:2010(R)2012 |
| Art 3.1(b) | EMC | ETSI EN 301 489-1 V2.2.3(2019-11),<br>ETSI EN 301 489-17 V3.2.4(2020-09) |
| Art 3.2 | Radio | ETSIEN 300 328 V2.2.2(2019-07) |

Shenzhen, 2023/1/10
Place, date

Zhou Saixi, General Manager
Name and position

Download Phone App **AirBP**

iOS: App Store

Android: Google Play

Contact us: service@getwellue.com

Website: www.getwellue.com

PN: 255-05488-00 Version: C

Model: BP1/BP1A Date: Jan, 2023

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