Wrist Type Blood Pressure Monitor

BPM32B

EN




IP 22 RoHS REACH MD

EC REP

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30175 Hannover Germany

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China, AViTA(WUJIANG)

Importer

Distributor

INSTRUCTION MANUAL
Please read this instruction manual carefully before operating this unit

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Intended Use

The product automatically measures human beings Systolic, Diastolic blood pressure and pulse rate by oscillometric method. The measurement results are displayed on the LCD. Measurement position is at human being's wrist. The intended use of this over-the-counter device is for adults with wrist circumference ranging from 125 mm to 210 mm (Approx.4.9 ~ 8.3 inches) and for home use. When the device detects the appearance of irregular heartbeats during measurement, an indicated symbol will appear with measuring readings.
This device is designed only for adults.

Contra-indications

Do not use in this case. (e.g. common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, patient motion, trembling, shivering, handicapped)

⚠ CAUTION:

- Beware of blood flow interference and resulting harmful injury to the patient caused by continuous cuff pressure.
- Pressurization of the cuff can temporarily cause loss of function of monitoring ME equipment simultaneously being used on the same limb.
- Reading can be affected by the measurement site, the position of the patient, exercise, or patient's physiologic condition.
- Automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.
- Frequent measurements can cause injury to the patient due to blood flow interference.
- Check that operation of the automated sphygmomanometer does not result in prolonged impairment of patient blood circulation.
- Retake the measurement if unexpected readings are obtained
- Ensure that the cuff is not placed on an arm in which the arteries or

veins are undergoing medical treatment, e.g., intravascular access or therapy, or an arteriovenous (AV) shunt.

- This product is suitable for use in the home healthcare environment.
- Keep this device out of the reach of children. Strangulation may result from baby or child entanglement in cables.
- Please keep this device away from pets, pests, and children.
- Preventing potential allergic reaction, please avoid the device in direct contact to patient's wound.
- Do not use with pregnant or pre-eclamptic patients
- Do not use the cuff on people who have undergone a mastectomy.
- Do not apply the cuff over a wound, as this can cause further injury.
- Do not apply the cuff other than the original manufacturer provided.
- Do not use this device other than the intended purposes.
- Do not use in these cases (e.g. Device for use in an ambulance, helicopter or professional environment)
- Cuff pressure 0 – 300 mmHg
- Reduction rate: ≦30S Refer to IEC 80601-2-30

- No modification of this equipment is allowed.
- High BMI health condition users may result varied.

Important Information Before Use

1. Blood pressure measurements should only be interpreted by a physician or a trained health care professional who is familiar with your medical history. Through regular use of this device and recording of your measurements, you can keep your physician informed of the changes in your blood pressure.
2. Perform your measurement in a quiet place. You should be seated in a relaxed position.
3. Avoid smoking, eating, taking medication, alcohol consumption or physical activity 30 minutes prior to taking a reading. If you are exhibiting signs of stress, avoid taking your measurement until the feeling subsides.
4. Rest 15 minutes prior to taking a reading.

5. Remove any constrictive clothing or jewelry that may interfere with the cuff placement.
6. Keep the monitor stable during measurement to achieve an accurate reading. Remain still; do not talk during the measurement.
7. Record your daily blood pressure and pulse readings on a chart.
8. Take your readings at the same time, each day or as recommended by your physician to get an accurate indication of change in your true blood pressure.
9. Wait a minimum of 15 minutes between readings to allow for the blood vessels to return to normal. The wait time may vary depending on your individual physiological characteristics.
10. Although such cases are rare, for those with an extremely weak pulse or irregular pulse, errors may result which prevent proper

measurement. If abnormal variations are noticed, consult with your physician or trained healthcare professional.

11. This device is intended for adult use. While taking a measurement, you can stop the inflation or deflation process of the cuff at any time by pressing the POWER button.
12. If any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

For Customer Service, the blood pressure monitor is calibrated when manufactured; it is recommended that the accuracy should be maintained and calibrated by manufacture triennially (every 3 years). To obtain the service please contact AViTA Corp. for the address of the repair location. Enclose with the Proof of Purchase. Include $10.00 USD

for the return shipping and handling. Accompany with a letter, with your name, address, phone number, and description of the specific problem or routine check-up. Pack the device carefully with bubble wraps (if there is) to prevent damages cause during transit. Due to possible losses in transit, it is recommended insuring the device with return receipt requested. If in any way of assistance of setting up, using, maintaining or to report unexpected operation/adverse events please contact manufacturer or local representative for further assistance.

FEDERAL COMMUNICATIONS COMMISSION INTERFERENCE STATEMENT

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.

CAUTION:
Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

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.

RF exposure warning

The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.

The equipment must not be co-located or operating in conjunction with any other antenna or transmitter.

Canada, Industry Canada (IC) Notices

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada’ s licence-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

Canada, avis d'Industry Canada (IC)

L’ émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d’ Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L’ exploitation est autorisée aux deux conditions suivantes :

(1) L’ appareil ne doit pas produire de brouillage;

(2) L’ appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d’ en compromettre le fonctionnement.

Blood Pressure Monitor Features

1. Hypertension Indicator(WHO indicator)

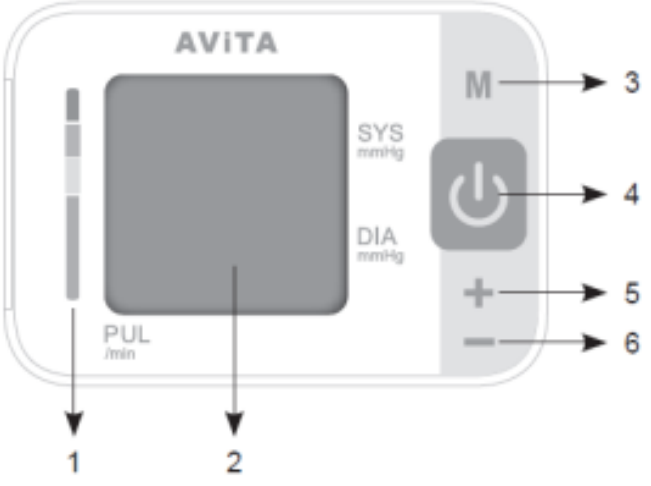
2. LCD Display

3. Memory Recall Button

4. Power Button

5. Advance Button

6. Retrogress Button



Description of LCD Display

88	Memory sets
M3	Memory Symbol
AVG	Average Measurement Symbol
	Low Battery Symbol
	Inflation Symbol(Positioning Indicator Up)
	Deflation Symbol(Positioning Indicator Down)
18-38	Date

Time

Digital Display

Heartbeat Symbol

Hypertension Indicator

Irregular Heart Beat Symbol

Positioning Indicator “OK”

Battery Installation

Low battery warning:

It is necessary to replace the batteries when the Low Battery symbol appears on the display, or when the display does not turn on after the POWER button is pressed.

Replacing the Battery:

- Slide the battery cover on the bottom of the monitor.
- Insert or replace 2 x 1.5 V AAA batteries into the battery compartment, ensuring to match the indicated polarity symbols. Always use new batteries.
- Replace the battery cover.

Battery-operated

- Always use NEW batteries; never mix old and new batteries.
- Please properly dispose of the batteries away from small children

and heat.
- It is recommended to remove the batteries if the unit will not be used for an extended period of time.
- Batteries must be disposed of in accordance with local environmental and institutional policies.
- Remove the battery during extended storage.
- It is recommended not to use rechargeable, unqualified or different spec battery may damage the device or cause circuit shortcut.

Setting the Date and Time

It is necessary to set the date and time for the unit every time batteries are initially installed or replaced.

(1) After replacing batteries, the "Year" will begin to flash on the display.

(2) Press the "+" button to advance or "-" button to retrogress the display to the desired "Year", press "M" button to

confirm the “Year”.

(3) Next, the “Month” will blink. Repeat steps 2 to set the “Month” and “Day”, then “hour”, then “Minute”.

(4) After setting the minute, the unit will automatically exit out or press power button the date/time setting mode and briefly show the word OFF before shutting down.

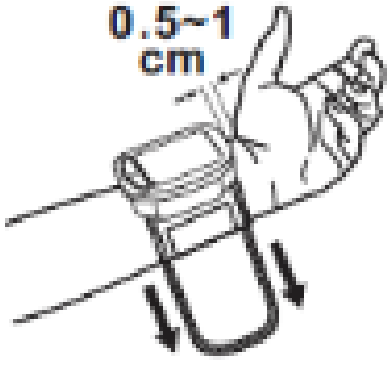
Applying Your Cuff

It is important to avoid smoking, eating, taking medication, alcohol consumption or physical activity 30 minutes prior to taking a reading. If for any reason you are unable to or should not use your left wrist, please modify the instructions for cuff application to your right wrist. Your physician can help you identify which wrist is best for you to take measurements from.

- Remove any constrictive clothing or jewelry that may interfere with cuff placement.
- Be seated at a table or desk with your feet flat on the floor.
- Hold your wrist in front of you at heart level with your palm facing upward.
- Apply the preformed cuff to your wrist so that the digital display face is positioned on the inside area

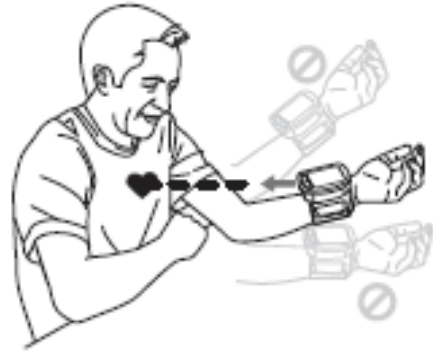
of your wrist facing you.

- Adjust the cuff approx. 1 cm from the edge of the head of the ulna bone.
- The cuff should fit comfortably, yet snugly around your wrist.
- Blood pressure naturally varies from one wrist to the other; therefore, measure your blood pressure on the same wrist to ensure comparability of the two readings.



Measurement of Pulse Rate and Blood Pressure

Please read the preceding portions of this manual prior to taking your first reading.



(1) Rest your elbow on a solid surface with your palm facing upward. Elevate your wrist so that the cuff is at the same level as your heart. Relax your left hand.

(2) Press the POWER button. This will turn the power on.

(3) While your position is improper, the Positioning symbol and the Positioning indicator "▲" or "▼" flash to guide you up or down your wrists, when you are in proper position the Positioning symbol "OK" flash. After the Positioning symbol flash for 3 times, the wrist cuff will start to inflate automatically.

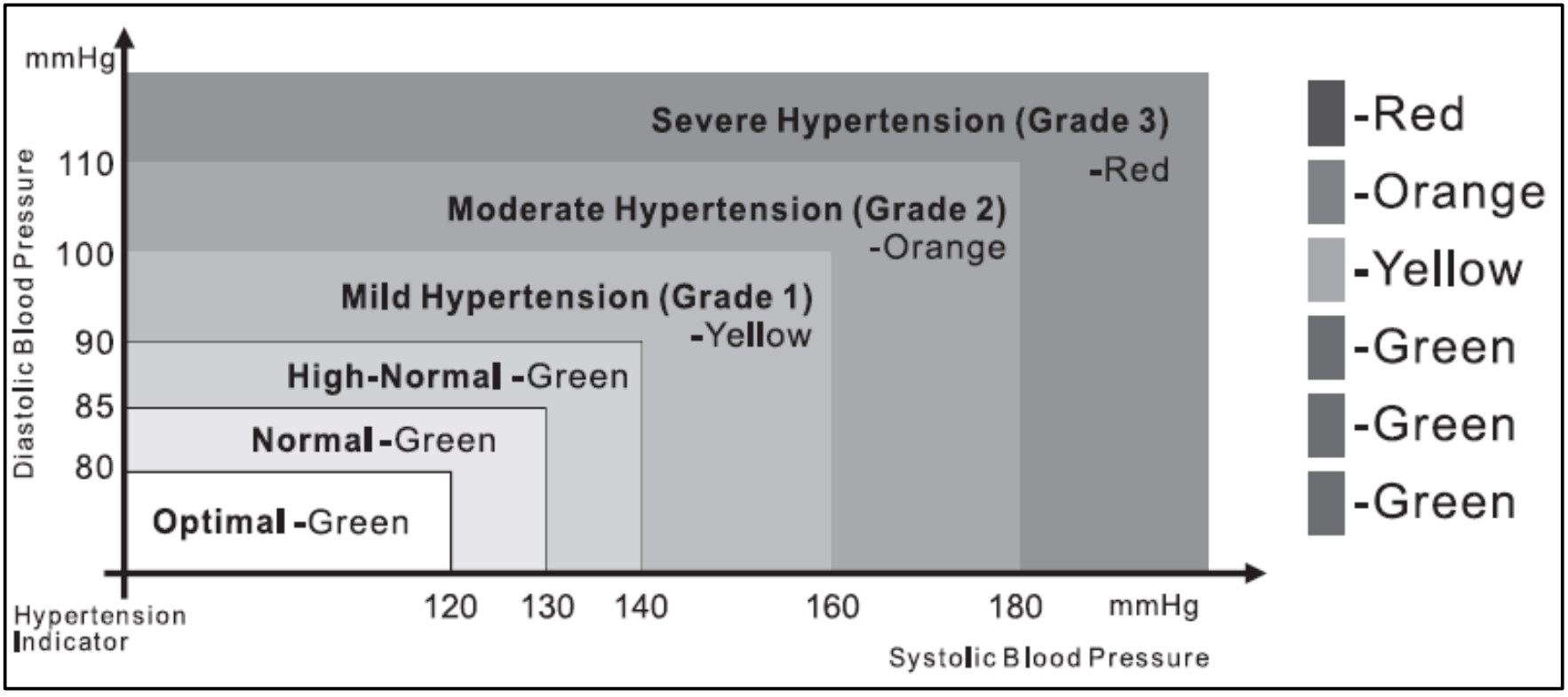
(4) The Wrist Positioning Guide can be used as an aid to help an end user determine if the device is at an appropriate position.

(5) The measurement starts automatically once the correct position has been obtained. Do not move or speak while the measurement is in progress.
(6) The cuff will automatically begin to inflate, with the display showing the increasing pressure in the cuff. As the pressure increases, an arrow pointing up will appear on the display.
(7) To detect the heartbeat, the heartbeat symbol will appear and continuous flashes on the LCD display.
(8) Your blood pressure measurement and pulse will display simultaneously on the screen.
(9) The Hypertension Indicator will indicate your reading range on the display separately.
(10) The reading will automatically be stored in memory.(You can press ″ + ″ or ″ - ″ button in standby mode to select User1 or User2 as the default storage zone.)
(11) Select POWER to turn the unit off and conserve energy and battery life. The unit will automatically shut-off approximately 2

minutes.

Hypertension Indicator

This monitor comes equipped with a Hypertension Indicator that automatically compares each reading to defined levels established by the World Health Organization and provides a helpful cue if your reading falls into one of the stages that could potentially indicate increased risk. Please note that cues provided by this monitor are only intended to assist you in using this table. The table and cues are only provided for convenience to help you understand to the level information. They are not a substitute for a medical examination by your physician. It is important for you to consult with your physician regularly. Your range as well as the point at which you may actually be considered to be at risk.


mmHg
Diastolic Blood Pressure
110
100
90
85
80
Severe Hypertension (Grade 3)
-Red
Moderate Hypertension (Grade 2)
-Orange
Mild Hypertension (Grade 1)
-Yellow
High-Normal -Green
Normal -Green
Optimal -Green
Hypertension Indicator
120
130
140
160
180
mmHg
Systolic Blood Pressure
-Red
-Orange
-Yellow
-Green
-Green
-Green

Irregular Heartbeat Detector

Your digital blood pressure monitor features an Irregular Heartbeat Detector. Irregular Heartbeats may influence the results of the measurement. If the monitor detects the Irregular Heartbeats during measurement, the symbol will appear on the display with the measurement values. You can take another measurement to make sure the values are not influenced by moving during measurement or Irregular Heartbeat.

The appearance of the icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is not a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

INPORTANT INFORMATION:

This blood pressure monitor is not designed for use by people with arrhythmias nor for diagnosing or treating an arrhythmia problem. As a safeguard, we recommend that if you have arrhythmias such as atrial or ventricular premature beats and atrial fibrillation or any other special conditions you should check with your physician before using your blood pressure monitor.

Memory Function

Recalling Measurements in Memory:

(1) Press and release the "M" button. The unit will first display the average of the last 3 stored measurements.

(2) Continue to press the "M" button to successively view the next previously stored measurements. Measurements will appear on the display from most current to oldest; the memory number will appear on the lower right corner.

(3) All results for a given measurement will display, including measurement results, pulse rate, Hypertension Indicator, and date/time stamp.

(4) When the number of readings exceeds 100, the oldest data will be replaced with the new record.

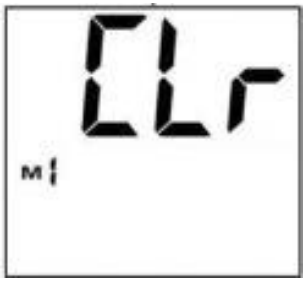
(5) Press the Power button to turn the monitor OFF at any time during review of the stored measurements.

User memory:
To select the relevant user memory, press the button "+" or "-" when the device is switched off.

Average values:

- A3 showed on the display.
  The average value of the last 3 stored measurements in this user memory is displayed.
- Press the button M.
- AM showed on the display.
- The average value of the morning measurements for the last 7 days is displayed (morning: 5 a.m. – 9 a.m.).
- Press the button M.
- PM showed on the display.
- The average value of the evening measurements for the last 7 days is displayed (evening: 6 p.m. – 8 p.m.).

Clearing Measurements from Memory:
From power display off, press and hold down the “M” button until the display shows CLr. This indicates that all measurements have been erased.



Data Transferring

This product is a wrist type blood pressure monitor. Design without entering personal information. The device has a transmission function. During the transmission process, the measurement data is designed to be encrypted, and will not be tampered with unauthorized access nor retrieve user-related information. The firmware and software of the product have been pre-programmed in the production stage. Both the burned in microcontroller programmer and the software were designed encrypted; there is no concern about the software safety.

Bluetooth function requirement:

An Android device with Android version 4.3 or above and hardware support for Bluetooth 4.2.

An iOS device with iOS version 5 or above and hardware support for Bluetooth 4.2.

Note:

Please refer to the instruction manual of your smart phone for how to activate the Bluetooth function.

Set Up Process

(1) Please determine your mobile phone or computer has BLE4.2.
(2) Turn on the BPM32B, it means BPM32B is under broadcast condition.
(3) Please check the connecting condition from your mobile phone or computer. The device name should be “BPM32B”.
(4) Every measure reading will be transfer to your mobile phone or computer automatically.

You can send results in memory zone as following step

(1) 1. Press Memory recall button of blood pressure monitor to enter memory mode. The symbol AVG and M will appear on the display and the number of memory index is “A3”.

(2) 2. Turn on the Bluetooth function of device to search the blood pressure monitor. Then the blood pressure monitor will be searched and connected the Bluetooth device.

(3) 3. After the connection is completed, you can press memory recall button to display the memory result on LCD. Each result showed on LCD, the result will be transmitted by Bluetooth immediately.

Error Codes

Error Code	Cause	Corrective Action
Err 00	No pulse or detect pulses not enough.	Take off heavy clothes and retry again.
Err 01	Leakage in Cuff Pressure/Inflation too low. overpressure protection	The wrist cuff is not fastened properly.

Error Code	Cause	Corrective Action
Err 02	Measured abnormal values.	Take a rest for 3~5 minutes. Re-apply the cuff and take a measurement again.
Err 03	Inflation fault.	Re-apply the cuff and take a measurement again.
Err	Memory error.	Take off batteries to reboot the device, then take another measurement.
	Low batteries	Replace all batteries with new ones.

Troubleshooting

Problem	Cause	Remedy
The reading is extremely low (or high).	The wrist cuff is not at heart level.	Measure while in the correct posture.
	The cuff is not wrapped snugly around the wrist.	Wrap the cuff correctly.
	The arms and shoulders are tense.	Relax and try taking the measurement again.
	Movement or talking during measurement.	Remain still and do not talk during measurement.

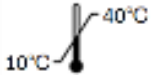
Problem	Cause	Remedy
The blood pressure is different each time. The reading is extremely low (or high).		Blood pressure readings constantly vary with time of day and how relaxed you are. Take several deep breaths and try to remain relaxed before taking a measurement.
Nothing happens when you press the buttons.	The batteries have been inserted incorrectly	Insert the batteries with the correct (+/-) polarity. Refer to 5.1.
Overpressure protection		The machine must be adjusted according to the instruction manual and with professional. equipment

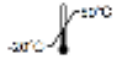
Problem	Cause	Remedy
Errors with wrist positional		The machine must be adjusted according to the instruction manual and with professional

Cleaning and Disinfecting

- Only use a soft, damp cloth to clean the monitor. Please do not use thinner, alcohol, detergents or solvents.
- The cuff can be cleaned carefully using a slightly damp cloth and mild soap solution. Do not completely immerse the cuff in water.
- It is recommended to clean and disinfect the cuff regularly or after each use, especially when used by several users, to prevent infection. The cuff should be disinfected, particularly on the inside, by wiping with a disinfectant. Use a disinfectant that is compatible with the cuff materials, e.g. 75 % ethanol or isopropyl alcohol.
- Keep the monitor in the appropriate carriage to protect it from external influences.

Technical Specification

- Measuring range :
  Blood Pressure : 40~255 mmHg
  Pulse Rate : 40~199 beats/min
- Calibration Accuracy :
  Pressure : ± 3 mmHg
  Pulse rate : ± 4% of reading
- Operating environment :
  10℃~40℃ (50℉~104℉) 

  15% to 85% relative humidity (non-condensing)
  Atmospheric Pressure: 700~1060 hPa
- Storage/ Transportation environment :
  -20℃~+50℃ (-4℉~+122℉) 
  15% to 85% relative air humidity (non-condensing)
  Atmospheric Pressure: 700~1060 hPa
- Power Source : 2 x 1.5 V LR03 (AAA) alkaline

- Weight : approx. 110g (exclude batteries)
- Dimensions : approx. 85mm × 60mm × 24.4mm (L×W×H)
- Cuff circumference : approx. 12.5~21 cm
- Lifetime : 3 years
- Battery life: above 300 times

EMC Tables

BPM32B is intended for use in the electromagnetic environment specified below. The customer or the user of **BPM32B** must make sure that it is used in such an environment.		
Guidance and manufacturer’ s declaration - Electromagnetic emissions		
Phenomenon	CISPR 11 Group 1 Class A (Not BLE Function) Group 2 Class A (With BLE Function)	CISPR 11 Group 1 Class B (Not BLE Function) Group 2 Class B (With BLE Function)
Conducted and radiated RF MISSIONS	Not applicable (Note: Power by Battery or DC Input) Only the AC input needs to be tested	
Harmonic distortion	Not applicable (Note: Power by Battery or DC Input) Only the AC input needs to be tested	
Voltage fluctuations and flickering	CISPR 11 Group 1 Class A (Not BLE Function)	

<table>
<tr><td colspan="2"></td><td colspan="2">Group 2 Class A (With BLE Function)</td></tr>
<tr><td colspan="4">a) The equipment is suitable for use in Home Health Environments and Professional Health Care Environments limited to patient rooms and respiratory treatment facilities in hospital or clinics. The more restrictive acceptance limits of Group 1 Class B (CISPR 11) have been considered and applied. The equipment is suitable for use in the mentioned environments when directly connected to the Public Mains Network.
b) The test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEM used will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard.</td></tr>
<tr><td colspan="4">Guidance and manufacturer’ s declaration - Electromagnetic immunity - Enclosure port</td></tr>
<tr><td rowspan="2">Phenomenon</td><td rowspan="2">Basic EMC standard or test method</td><td colspan="2">Immunity test levels</td></tr>
<tr><td>Professional healthcare facility environment</td><td>HOME HEALTHCARE ENVIRONMENT</td></tr>
<tr><td>ELECTROSTATIC</td><td>IEC 61000-4-2</td><td colspan="2">± 8kV contact</td></tr>
</table>

DISCHARGE		± 2 kV, ±4kV ±, ±8 kV, ±15 kV air	
Radiated RF EM fields	IEC 61000-4-3	a)	10 V/m b) 80MHz - 2.7 GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	COMPLIANT NOTE: Further information about distances to be maintained between portable and mobile RF communications equipment (transmitters) and the **BPM32B** can be requested from supplier using the contact information provided in this manual. However, it is advisable to keep the electromechanical aerosol equipment at an adequate distance of, at least, 0.5 m from mobile phones or other RF communications transmitters to minimise possible interference.	
RATED power	IEC 61000-4-8	30 A/m c)	

frequency magnetic fields.		50 Hz or 60 Hz
a) The equipment is suitable for use in Home Health Environments and Professional Health Care Environments limited to patient rooms and respiratory treatment facilities in hospital or clinics. The more restrictive IMMUNITY acceptance limits have been considered and applied. b) Before modulation is applied. c) This test level assumes a minimum distance of at least 15 cm between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic fields.		

Explanation of Symbols

Symbol	Definition
CE 2797	The CE marking with the Registration Number of the Notified Body. This denotes the compliance of Regulation (EU) 2017/745
MD	Medical Device
	Manufacturer

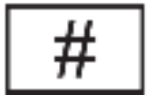
EC REP	Authorized representative in the European Community
	Date of manufacture (YYYY-MM-DD or YYYY-MM)
LOT	Batch code (YYMMWWWW)
SN	Serial number (YYMWWWXXXXX)

	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

	Caution
	Consult the instruction for use
	Disposal information: Should you wish to dispose of the article, do so in accordance with current regulations. Details are available from your local authority. WEEE 2012/19/EU Directives
RoHS	This product fulfilling the requirements of the RoHS Directive 2011/65/EU.

REACH	This product fulfilling the requirements of the REACH Directive EC 1907/2006 and its amendments, do not contain Substances of Very High Concern in concentration above the limit of 0.1 %. No substance(s) is/are present in the parts of the product above the concentration of 0.1 % weight by weight.
	Stand-by
	Device classification type BF

IP 22	This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (protection against solid foreign objects of 12.5mm ø and greater and against vertically falling water drops when enclosure tiled up to 15°)
	The empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.
	Importer

	Distributor
	Model Number
	Country of Manufacturer
	Unique Device Identifier

	Keep away from sunlight

Electronic IFU available at http://www.avita.com.tw