AViTA Wrist Type Blood Pressure Monitor



# Model: # BPM13B

# INSTRUCTION MANUAL

PLEASE READ THIS INSTRUCTION MANUAL COMPLETELY BEFORE OPERATING THIS UNIT **FN** 





٣

9F., No. 78, Sec. 1, Kwang Fu Rd., San Chung Dist., New Taipei City 24158, Taiwan (R.O.C)

Made in China

Importer

Distributor

#### INSTRUCTION MANUAL

#### Contents

1. Introduction	1
2. Important Information Before Use	2
3. Blood Pressure Monitor Features	
4 Description of ICD Display	6
5. Battery Installation	8
6. Setting the Date and Time	
7. Applying Your Cuff	
8. Taking a blood pressure measurement 9. Heartbeat Remind	
9. Heartbeat Remind	
10. Hypertension Indicator	
11. Memory Function	
11. Memory Function 12. Troubleshooting	
13. Error Codes	24

14. Data Transferring	
15. FEDERAL COMMUNICATIONS COMMISSION	
INTERFERENCE STATEMENT	
16. Care and Maintenance	
17. Technical Specification	
18. EMC Tables	
19. Explanation of Symbols	

## 1. Introduction

BPM13B Series Blood Pressure Monitor applies the Oscillometric method to measure human systolic / diastolic blood pressure and heart rate. This device is designed only for adults.

CAUTION:

- No modification of this equipment is allowed.
- Keep your equipment out of the reach of children, pets and pest.
- The Patient is an intended operator.
- Risk of explosion if battery is replaced by an incorrect type.
- Dispose of used batteries according to the instructions.

# 2. Important Information Before Use

When using this product, please be sure to follow all the notes listed below. Any action against these notices may cause injury or affect the accuracy.

- WARNING
- Do not modify this equipment without authorization of the manufacturer.
- 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.
- Perform your measurement in a quiet place. You should be seated in a relaxed position.
- 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.
- Rest 15 minutes prior to taking a reading.
- Remove any constrictive clothing or jewelry that may interfere with the cuff placement.
- Keep the monitor stable during measurement to achieve an accurate reading. Remain still; do not talk during the measurement.
- Record your daily blood pressure and pulse readings on a chart.
- 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.
- Wait a minimum of 2~3 minutes between readings to allow for the blood vessels to return to normal. The wait time may vary depending on your individual physiological characteristics.
- 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.

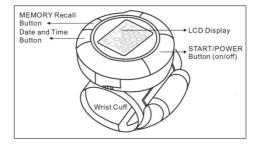
- This device is intended for adult use. While taking a measurement, you can stop the inflation or deflation process of the cuff at any time by pressing the POWER button.
- It is recommended that the accuracy should be checked by the manufacturer every two years.
- If you would require any assistance during setting up, using or maintaining, please contact the manufacturer.

Note.

Under any circumstances, the measurement taking result is ONLY for reference.

Any further medical action should follow the advice of doctors.

#### 3. Blood Pressure Monitor Features



# 4. Description of LCD Display

- **BB** Memory sets
- Ma Memory Symbol
- AVG Average Measurement Symbol
- Low Battery Symbol
  - 1 Inflation Symbol
  - Deflation Symbol
- 18-38 Date



Hypertension Indicator



Irregular Heart Beat Symbol

#### 5. 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:

- Open 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.
- Close the battery cover.

Battery-operated

- Always use NEW batteries; never mix old and new batteries.

- Do not use rechargeable batteries; rechargeable batteries can vary greatly in quality and strength. Use of rechargeable batteries may affect the performance of this device.
- 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.

## 6. Setting the Date and Time

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

- (1) When the unit is off (a blank display screen) or after replacing batteries, press and release the "Date and Time" button; the "Year" will begin to flash on the display.
- (2) Press the "MEMORY" button to advance the display to the desired "Year", press "POWER" button to confirm the "Year".
- (3) Next, the "Month" will blink. Repeat steps 1 and 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.

# 7. 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.



Applying Your Cuff

- 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 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 0.5~1 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.

# 8. Taking a blood pressure measurement

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

- 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) After the self-test, the values for the last reading will appear on the display. The blood pressure monitor start to measure. Do not move or speak while the measurement is in progress.
- (4) 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.
- (5) When the inflation has reached optimum level, the display will begin to show the decreasing pressure; the screen will display an arrow pointing down while you feel the pressure of the cuff

decrease.

- (6) To detect the heartbeat, the heartbeat symbol will appear and continuous flashes on the LCD display.
- (7) Your blood pressure measurement and pulse will display simultaneously on the screen.
- (8) The Hypertension Indicator will indicate your reading range on the display separately.
- (9) The reading will automatically be stored in memory.
- (10) Select POWER to turn the unit off and conserve energy and battery life. The unit will automatically shut-off approximately 2 minutes.

#### 9. Heartbeat Remind

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.

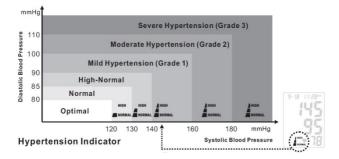
The appearance of the icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is not a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac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

## **10. 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.



## 11. Memory Function

Recalling Measurements in Memory:

- (1) Press and release the "MEMORY" button. The unit will first display the average of the last 3 stored measurements.
- (2) Continue to press the "MEMORY" 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 left 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 60, 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.

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



#### 12. Troubleshooting

Problem	Cause	Remedy
The reading	The wrist cuff is not at	Measure while in the correct
is extremely	heart level.	posture.
low (or	The cuff is not wrapped	Wrap the cuff correctly.
high).	snugly around the	
	wrist.	
	The arms and	Relax and try taking the
	shoulders are tense.	measurement again.
	Movement or talking	Remain still and do not talk
	during measurement.	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.
	The batteries have been inserted incorrectly	Insert the batteries with the correct (+/-) polarity.
Overpressure protection		The machine must be adjusted according to the instruction manual and with professional. equipment

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

#### 13. Error Codes

Error Code	Cause	Corrective Action
Err 00	No pulse or detect	Take off heavy clothes and retry again.
	pulses not enough.	
Err 01	Leakage in Cuff	The wrist cuff is not fastened properly.
	Pressure/Inflation too	Reapply the cuff, and take a
	low.	measurement again.
Err 02	Measured abnormal	Take a rest for 3~5 minutes. Re-apply
	values.	the cuff and take a measurement again.
Err 03	Deflation fault.	Re-apply the cuff and take a
		measurement again.
Err	Memory error.	Take off batteries to reboot the device
		then take another measurement.

Error Code	Cause	Corrective Action
	Low batteries	Replace all batteries with new ones.

## 14. Data Transferring

Bluetooth function

What You Need

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. All devices Apple released since the iPhone do, the older ones don't.

Note:

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

Set Up Process

(1) Download an app which supports Bluetooth 4.0 from the iTune App Store or Google Play.

- (2) Enable Bluetooth on your mobile device.
- (3) Open the app and activate the function.
- (4) Turn on the BPM13B.
- (5) The app should automatically detect your BPM13B. Tap the BPM13B that is showed in the device list.
- (6) Your BPM13B is now successfully connected to your mobile device. Every measure reading will be transfer to your mobile device automatically.
- You can send results in memory zone as following step
  - 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.

# 15. 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.

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.

#### 16. Care and Maintenance

- Clean the device and wrist cuff carefully only with a slightly moistened cloth.
- Do not immerse the device in water. It may cause damage if water enters.
- Do not use any gas, strong detergent, or solvents to clean the device, including the wrist cuff.
- Use a soft, dry cloth to clean your monitor.
- Do not store in direct sunlight, dust or excessive humidity.
- Avoid extreme temperatures.
- Do not disassemble the monitor or cuff.
- Remove batteries if the monitor will not be used for an extensive period of time.

## 17. Technical Specification

- Measuring range : Blood Pressure : 30~280 mmHg Pulse Rate : 40~199 beats/min
- Calibration Accuracy : Pressure : ± 3 mmHg Pulse rate : ± 4% of reading
- Operating environment :  $10^{\circ}C \sim 40^{\circ}C$  ( $50^{\circ}F \sim 104^{\circ}F$ ) with relative humidity up to 85% (non condensing) Atmospheric Pressure:  $700 \sim 1060$  hPa
- Storage/ Transportation environment : -20°C~+50°C (-4°F~+122°F) with relative humidity up to 85% (non condensing) Atmospheric Pressure: 700~1060 hPa
- Power Source : 2 x 1.5 V AAA batteries

- Weight : approx. 115g (exclude batteries)
- Dimensions : approx. 80mm × 84mm × 33mm (W×H×D)
- Cuff circumference : approx. 12.5~21 cm

## 18. EMC Tables

**BPM13B** is intended for use in the electromagnetic environment specified below. The customer or the user of **BPM13B** must make sure that it is used in such an environment.

Guidance and manufacturer's declaration - Electromagnetic emissions

Phenomenon	Professional healthcare facility environment a)	HOME HEALTHCARE ENVIRONMENT a)
Conducted and radiated RF EMISSIONS	a)	CISPR 11 Group 1 Class B
Harmonic distortion	Not applicable	
Voltage fluctuations and flickering	Not applicable	
<ul> <li>a) The equipment is suitable for use in Home Health Environments and Professional Health Care Environments limited to patient rooms and</li> </ul>		

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.

Guidance and manufacturer's declaration - Electromagnetic immunity - Enclosure port

	baile poile		
Phenomenon		Immunity test levels	
	standard or test method		HOME HEALTHCARE ENVIRONMENT
		environment	
ELECTROSTATIC	IEC 61000-4-2		
DISCHARGE		± 2 kV, ±4kV	±, ±8 kV, ±15 kV air
Radiated RF EM	IEC 61000-4-3	a)	10 V/m b) 80MHz - 2.7

fields		GHz 80% AM at 1kHz
	IEC 61000-4-3	COMPLIANT NOTE: Further information about distances to be maintained between portable and mobile RF communications equipment (transmitters) and the <b>BPM13B</b> can be requested from supplier using the contact information provided in this manual. However, it is advisable to keep the 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 frequency magnetic fields.	IEC 61000-4-8	30 A/m c) 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.

## 19. Explanation of Symbols

Symbol	Definition
MD	Medical Device
	Manufacturer
~~	Date of manufacture (YYYY-MM-DD or YYYY-MM or YYYY)

LOT	Batch code LOT WWWXXXXX LOT: Lot Number; WWW: working sheet; XXXXX: serial no.
SN	Serial number SN YYMWWWXXXXX YY: year; M:month; WWW: working sheet; XXXXX: serial no.
Ĵ	Keep dry
X	Temperature limit

<u></u>	Humidity limitation
<b>\$•</b> \$	Atmospheric pressure limitation
$\triangle$	Caution

	Consult the instruction for use
X	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.
Ċ	Stand-by
Ŕ	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°)

X	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
UDI	Unique Device Identifier

72-B13BMN-AV11 2022/1/6