

Arm Type Bluetooth Blood Pressure Monitor

Model No.: BPM63ZB



INSTRUCTION MANUAL

PLEASE READ THIS INSTRUCTION MANUAL COMPLETELY
BEFORE OPERATING THIS UNIT.

Index

Intended Use	1
Important Information Before Use	2
Product Identification	3
Description of LCD Display	3
Battery Installation	4
Setting the Date and Time	5
Placement of the Pressure Sleeve	6
Measurement of Pulse Rate and Blood Pressure	8
Irregular Heartbeat Detector	10
World Health Organization (WHO)	10
Memory Function	11
Operating the Bluetooth function	12
Troubleshooting	13
Error Codes	13
Care and Maintenance	14
Applied Standards	14
Technical Specification	14
FCC Statement	15
EMC Tables	16

Intended Use

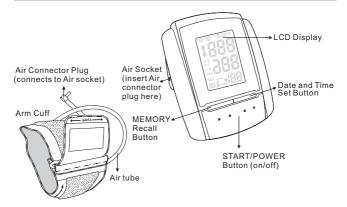
BPM63ZB Series Blood Pressure Monitor applies the Oscillometric method to measure human systolic / diastolic blood pressure and heart rate. All values are shown on the LCD monitor. This device is designed only for adults.

Important Information Before Use

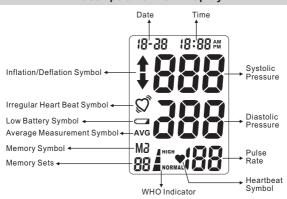
- 1. Blood pressure measurements should only be interpreted by a physician or a trained health care professional who is familiar with your medical history. Through regular use of this device and recording of your measurements, you can keep your physician informed of the changes in your blood pressure.
- 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.
- 4. 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.
- 7. 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 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.

Under any circumstances, the measurement taking result is ONLY for reference.
for reference.
Any further medical action should follow the advice of doctors.

Product Identification



Description of LCD Display



Battery Installation

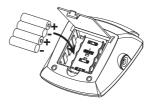
Low battery warning:

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:

- 1. Press down on latch and lift the cover on the bottom of the monitor.
- Insert or replace 4 x 1.5 V AA batteries into the battery compartment, ensuring to match the indicated polarity symbols. Always use new batteries.
- 3. Replace the battery cover.



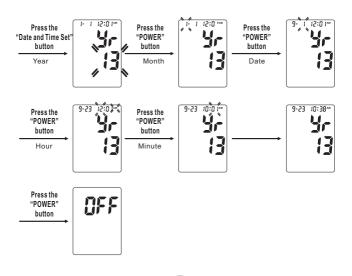
NOTE: Battery-operated

- 1. Please properly dispose of the batteries away from small children and heat.
- 2. It is recommended to remove the batteries if the unit will not be used for an extended period of time.
- 3. Batteries must be disposed of in accordance with local environmental and institutional policies.

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.

- While in power off mode, press the "Date and Time Set" button to enter Date and Time setting procedure and the Year value will begin to flash.
- 2. Press the "MEMORY Recall" button to advance the display to the desired year, press "POWER" button to confirm the year.
- 3. Next, the month will blink. Repeat step 2 to set the month and date, then hours, then minutes.
- 4. After setting the minutes, the unit will automatically exit out of the date/time setting mode and briefly show the word OFF before shutting down.



Placement of the Pressure Sleeve

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 arm, please modify the instructions for cuff application to your right arm. Your physician can help you identify which arm is best for you to take measurements from

- Remove any constrictive clothing or jewelry that may interfere with cuff placement.
- 2. Be seated at a table or desk with your feet flat on the floor.
- The cuff should not be plugged into the monitor until after the cuff is applied to your arm.
- Note:

Blood pressure naturally varies from one arm to the other; therefore, measure your blood pressure on the same arm to ensure comparability of the two readings.

- 4. Position the cuff on a solid surface with the tubing facing up and away from you. The metal ring/bar on the cuff should be to the left of the tubing.
- Open the cuff by pulling or rolling the bottom of the cuff to the right. This should open the cuff without fully unrolling it, creating a cylinder. Do not fully unwrap or unroll the cuff.
- Insert your left arm into the created cuff cylinder. Position the () mark over the main artery on the inside of your arm.
- The bottom edge of the cuff should be positioned approximately one inch above the elbow joint.

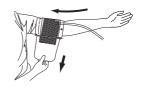






Placement of the Pressure Sleeve

8. Reaching underneath your left arm with your right hand, pull the end of the cuff towards your body to tighten the cuff.
Wrap and secure the cuff, making sure that the (\(\phi\)) mark remains in place as shown.



- The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger easily between your arm and the cuff.
- 10. The cuff size is suitable for use when the vertical 'index' mark is within the horizontal OK range. A different size cuff is needed if the 'index' mark is outside the OK range.



Note:

If you are not comfortable with applying your cuff, please seek the assistance of another member of your household or work with your physician to practice the cuff application. Incorrectly applied cuffs may result in inaccurate readings.

Measurement of Pulse Rate and Blood Pressure

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

1. Position the monitor on a flat, stable surface with the digital display in view.

- 2. Insert the cuff tubing connector into the port on the left side of your monitor.
- Rest your elbow on a solid surface with your palm facing upward. Elevate your arm so that the cuff is at the same level as your heart. Relax your left hand.



- 5. After the self-test, the values for the last reading will appear on the display.
- 6. The blood pressure monitor start to measure.
- 7. 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.
- 8. 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.









Measurement of Pulse Rate and Blood Pressure

9. To detect the heartbeat, the heartbeat symbol will appear and continuous flashes on the LCD display.



- 10. Your blood pressure measurement and pulse will display simultaneously on the screen.
- 11. The Hypertension Indicator will indicate your reading range on the display separately.



- Your reading will be automatically stored in "MEMORY Recall" Button.
- 13. Select POWER to turn the unit off and conserve energy and battery life. The unit will automatically shut-off approximately 2 minutes.

Irregular Heartbeat Detector

Your digital blood pressure monitor features an Irregular Heartbeat Detector. This feature allows users to accurately monitor blood pressure even if an irregular heartbeat should occur. When an irregular heartbeat is detected, the "" icon will appear on the display.



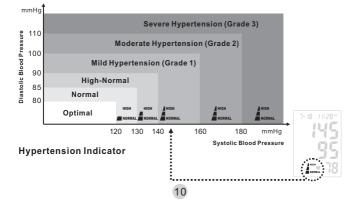


Note:

Please consult with your physician or trained healthcare professional for further information regarding an irregular heartbeat and if this symbol appears frequently.

World Health Organization (WHO)

This unit features our unique Hypertension Indicator. The World Health Organization has established globally accepted standards for the assessment of high or low blood pressure readings. The below chart should be considered only as a guideline, always consult with your physician or health care professional to interpret your individual results

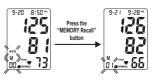


Memory Function

Recalling Measurements in Memory:

You can recall up to **60** measurements per memory bank, plus an average of last 3 currently stored measurements in memory to share with your physician or trained healthcare professional.

- 1. Press and release the "MEMORY Recall" Button. The unit will first display the average of last 3 currently stored measurements.
- Continue to press the "MEMORY Recall" 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.



- All results for a given measurement will display, including measurement results, pulse rate, Hypertension Indicator, Irregular Heartbeat alert, and date/time stamp.
- The memory bank stores up to 60 readings; when the number of readings exceeds 60, the oldest data will be replaced with the new record.
- 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 Recall" Button until the display shows CLr. This indicates that all measurements have been erased.



Operating the Bluetooth function

BPM63ZB is through the Bluetooth technology (BLE4.0) to transfer the related information of your blood pressure measurement. Please determine your device (Mobile Phone or Computer) has BLE4.0 equipped to support BPM63ZB operation. Currently, BPM63ZB can support the iOS and Android operating systems.

You can also 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 "00".



- 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.
- 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.



Troubleshooting

Problem	Probable Cause	Recommended Action
Nothing appears in	Batteries are drained.	Replace all batteries with new ones.
the display even when the power is turned on.	Battery are not correctly aligned with terminals.	Reinsert batteries in the correct position.
Low Battery Symbol	Batteries are drained.	Replace all batteries with new ones.
appears.	In colder temperatures batteries have weaker electrical charges.	Warm up the batteries, or use the device in a warmer setting.
Device operation time is inconsistent.	Different battery brands have different life spans.	Use Alkaline batteries and replace all batteries at the same time with same brand batteries.
No reading after measurement.	Batteries are drained.	Replace all batteries with new ones.
Suspicious blood pressure results.	Perhaps the cuff was improperly positioned.	Adjust patient and arm cuff to measure.
	Blood pressure naturally varies throughout the day.	Rest a while, relax and measure again.
Suspicious heart rate results.	Bodily movement during device use.	Refrain from moving during measurement.
	Measurement shortly after exercise or exposure to the outdoors.	Do not take measurements after exercise or coming back from the outdoors.
Power switches off automatically.	System design.	Push the power button again, and then begin measure again.
During measuring, air re-inflates.	It could be a normal action if the user's blood pressure is higher than the initial pressure value, the device automatically pumps to a higher pressure by 40mmHg each time.	Relax, and try to take a measure again.
	The arm cuff is not fastened properly.	Check that the arm cuff is fastened properly and retake the measurement.

Error Codes

Err Code	Meaning	Corrective Action
Err 0	No pulse or detect pulses not enough.	Take off heavy clothes and retry again.
Err 1	Leakage in Cuff Pressure/Inflation too low.	The arm cuff is not fastened properly. Reapply the cuff, and take a measurement again.
Err 2	Pressure fault.	Rest a while, relax and retry again.
Err 3	Deflation fault.	The arm cuff is not fastened properly. Reapply 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.

Care and Maintenance

- 1. Clean the device and arm cuff carefully only with a slightly moistened cloth.
- 2. 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 arm cuff.
- 4. Disconnect the cuff and tubing from the monitor prior to storing.
- 5. Do not use any liquids on the monitor or cuff.
- 6. Use a soft, dry cloth to clean your monitor.
- 7. Do not store in direct sunlight, dust or excessive humidity.
- 8. Avoid extreme temperatures.
- 9. Do not disassemble the monitor or cuff.
- 10. Remove batteries if the monitor will not be used for an extensive period of time.

Applied Standards

This product conforms to the provisions of the EC directive MDD (93/42/EEC). The following standards apply to design and/or manufacture of the products: • EN 1060-1

- Non-invasive sphygmomanometers-Part1 : General requirements
 FN 1060-3
- Non-invasive sphygmomanometers-Part 3 : Supplementary requirements for electro-Mechanical blood pressure measuring system - EN 1060-4
- Non-invasive sphygmomanometers Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
- · ANSI/AÁMI Sp10
- Electronic or automated sphygmomanometers
- ISO 14971
 Medical devices-Application of risk management to medical devices. The Classification
- according to IEC/EN 60601-1 sub-claues 5:
- Internally powered equipment
 IPX0
- Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide
- · Continuous operation

C €	TUV NO.
$\bigcap_{\mathbf{i}}$	Refer to instruction
†	Type BF equipment (Cuff)
X	The device shall be disposed in accordance with national laws after their useful lives
ш	Manufacturer's name and address
EC REP	Wellkang Ltd 29 Harley St. W1G 9QR LONDON, U.K.

Technical Specification

• Measuring range: Blood Pressure: 30~280 mmHg

Pulse Rate: 40~199 beats/min

Calibration Accuracy: Blood Pressure: ± 3 mmHg

Pulse rate: ± 4% of reading

• Operating environment : 10°C~40°C (50°F~104°F)

with relative humidity up to 85% (non condensing)

· Storage/ Transportation environment :

-20°C~+50°C (-4°F~+122°F) .20°L

with relative humidity up to 85% (non condensing)

Power Source: 4 x 1.5 V AA batteries

• Weight: approx. 275g (exclude batteries)

• Dimensions: approx. 113mm x 140mm x 57mm (W x H x D)

• Cuff circumference (M Size): approx. 22 ~ 33 cm (9" ~ 13")

FCC Statement

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 of the following measures:

- 1. Reorient or relocate the receiving antenna.
- 2. 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.
- 4. Consult the dealer or an experienced adio/TV technician for help.
- 5. FCC Caution: To assure continued compliance, (example use only shielded interface cables when connecting to computer or peripheral devices). Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.
- 6. 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.
- 7. This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be colocated or operating in conjunction with any other antenna or transmitter.

EMC Tables

Guidance and manufacturer's declaration-electromagnetic emissions

The BPM63ZB Arm Type Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the BPM63ZB Arm Type Blood Pressure Monitor should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	·	The BPM63ZB Arm Type Blood Pressure Monitor 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 RDM637R Arm Type Blood Proceurs Manitor is
Harmonic emissions IEC 61000-3-2	Not applicable	The BPM63ZB Arm Type Blood Pressure Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration-electromagnetic immunity

The BPM63ZB Arm Type Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the BPM63ZB Arm Type Blood Pressure Monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
	± 6 kV contact ± 8 kV air	contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

EMC Tables

Guidance and manufacturer's declaration-electromagnetic immunity

The BPM63ZB Arm Type Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the BPM63ZB Arm Type Blood Pressure Monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the BPM63ZB Arm Type Blood Pressure Monitor , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
			$ \begin{array}{lll} \text{d=1.2} \ \sqrt{P} \\ \text{d=1.2} \ \sqrt{P} \\ \text{d=2.3} \ \sqrt{P} \end{array} \begin{array}{lll} \text{80 MHz to 800 MHZ} \\ \text{800 MHz to 2,5 GHz} \end{array} $
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and b is the recommended separation distance in metres (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b .
			Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, 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 BPM63ZB Arm Type Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the BPM63ZB Arm Type Blood Pressure Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BPM63ZB Arm Type Blood Pressure Monitor.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

EMC Tables

Recommended separation distances between portable and mobile RF communications equipment and the BPM63ZB Arm Type Blood Pressure Monitor

The BPM63ZB Arm Type Blood Pressure Monitor is intended fo use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BPM63ZB Arm Type Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BPM63ZB Arm Type Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power	Separation distance according to frequency of transmitter m			
of transmitter W	150 kHz to 80 MHz d=1.2√P	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance of 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.

Manufacturer:

AViTA Corporation 9F, No.78, Sec.1, Kwang-Fu Rd., San-Chung District, 24158 New Taipei City, Taiwan

No.858, Jiao Tong Road, Wujiang Economic Development Zone Jiangsu Province, P.R.C. Postcode: 215200 Made in P.R.C.