Wellex

Arm Type Blood Pressure Monitor Model: BPM64R



INSTRUCTION MANUAL Please read this instruction manual carefully

before operating this unit.

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Introduction

BPM64R 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 and using the Bluetooth technology (BLE4.0) or USB to transfer the related information of your blood pressure measurement. 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.

Important Information Before Use

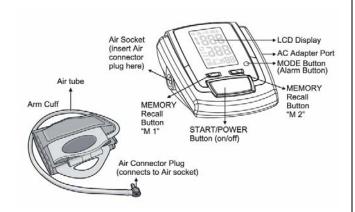
- When using this product, please be sure to follow all the notes listed below. Any action against these notices may cause injury or affect the accuracy.
- 1. WARNING Do not modify this equipment without authorization of the manufacturer.
- Blood pressure measurements should only be interpreted by a 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.
- 4. 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.

- 5. Rest 15 minutes prior to taking a reading.
- 6. 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.
- 10. 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.
- 11. 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.
- 12. 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.
- 13.It is recommended that the accuracy should be checked by the manufacturer every two years.
- 14.If you would require any assistance during setting up, using or maintaining, please contact the manufacturer.
- Under any circumstances, the measurement taking result is ONLY for reference.

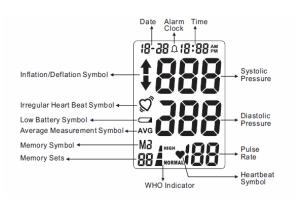
 Any further medical action should follow the advice of doctors.

Blood Pressure Monitor Features



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Description of LCD Display



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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.

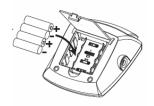


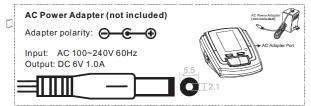
Replacing the Battery:

- 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.





Battery-operated

- Always use NEW batteries; never mix old and new batteries.
- 2. Do not use rechargeable batteries; rechargeable batteries can vary greatly in quality and strength.

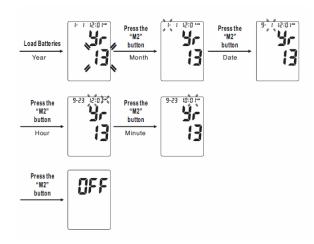
Use of rechargeable batteries may affect the performance of this device.

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

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. Loading 4 AA alkaline batteries; the Year value will begin to flash on the display.
- 2. Press the "M1" button to advance the display to the desired year, press "M2" button to confirm the year.
- 3. Next, the month will blink. Repeat steps 2 to set the month and date, then hours, then minutes.
- 4. After setting the minutes, the unit will automatically exit out or press power button of 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 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

1. Remove any constrictive clothing or jewelry that may interfere with cuff placement.

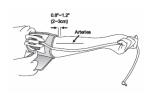


- 2. Be seated at a table or desk with your feet flat on the floor.
- 3. The cuff should not be plugged into the monitor until after the cuff is applied to your arm.

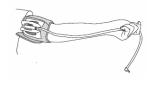


Blood pressure naturally varies from one arm to the other; therefore, measure your blood pressure on the same arm to ensure comparability of the two readings.

4. Unfold the Easy Cuff and apply to your left arm. Position the air tube over the main artery on the inside of your



5. The bottom edge of the cuff should be positioned approximately one inch above the elbow joint.



Reaching underneath your left arm with your right hand, pull the end of the cuff towards your body to tighten



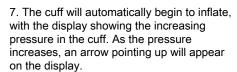
the cuff. Incorrectly applied cuffs may result in inaccurate readings or showing error message.

Taking a blood pressure measurement

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.
- 3. 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.
- 4. Press the POWER button. This will turn the power on.
- 5. After the self-test, the values for the last reading will appear on the display.
- 6. The blood pressure monitor start to measure.





- 8. As the cuff inflates, the monitor automatically determines your ideal inflation level. This monitor detects your blood pressure.

 9-23 10:38**
- 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

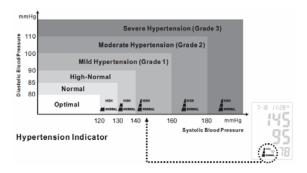
Your digital blood pressure monitor features an Irregular Heartbeat Detector. This feature allows users to accurately monitor blood pressure even if an irregular heartbeat should occur. When an irregular heartbeat is detected, the "\$\sigma\$" icon will appear on the display.



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.

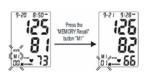


Memory Function

Recalling Measurements in Memory:

You can recall up to 90 measurements per memory bank, 180 total, plus an average of last 3 currently stored measurements in memory to share with your physician or trained healthcare professional.

 1. 1. Press and release the M1 or M2 button. The unit will first display the average of last 3 currently stored measurements.



Continue to press the M1
or M2 button to successively
view the next previously
stored measurements.

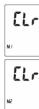


Measurements will appear on the display from most current to oldest; the memory number will appear on the lower left corner.

- All results for a given measurement will display, including measurement results, pulse rate,
 Hypertension Indicator, Irregular Heartbeat alert, and date/time stamp.
- 4. Each memory bank stores up to 90 readings; when the number of readings exceeds 90, 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 M1 button or the M2 button until the display shows CLr. This indicates that all measurements have been erased.



Troubleshooting

Problem	Probable Cause	Recommended Action
Nothing appears in the	Batteries are drained.	Replace all batteries with new ones.
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 wrist cuff to measure.
	Blood pressure naturally varies throughout the day	Rest a while, relax and measure again.
Suspicious heart rate	Bodily movement during device use.	Refrain from moving during measurement.
results.	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 wrist cuff is not fastened properly.	Check that the wrist cuff is fastened properly and retake the measurement.

Error Codes

Err	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 wrist 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 wrist 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.

Data Transferring

Bluetooth function:

What You Need

An Android device with Android version 4.3 or above and hardware support for Bluetooth 4.0.

An iOS device with iOS version 5 or above and hardware support for Bluetooth 4.0. All devices Apple released since the iPhone 4S (including the 4S) 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 BPM64R.
- The app should automatically detect your BPM64R.
 Tap the BPM64R that is showed in the device list.
- Your BPM64R 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 "00".
- 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.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.

USB function:

Connect the blood pressure monitor to your PC using the USB Cable. PL appears on the display. Begin the data transfer in the PC software. During the data transfer, an animation is shown on the display.

 A successful data transfer is displayed as in figure 1.

If the data transfer is unsuccessful, an error message appears as in figure 2.

In this case, interrupt the PC connection and start the data transfer again.

After 30 seconds of not being in use or if communication with the PC is interrupted, the blood pressure monitor switches itself off automatically.

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.
- 3. 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.

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:
 10oC~40oC (50oF~104oF)
 with relative humidity up to 85% (non condensing)

• Storage/ Transportation environment : -20oC~+50oC (-4oF~+122oF) with relative humidity up to 85% (non condensing)

• Power Source : 4 x 1.5 V AA batteries

· Weight: approx. 250g (exclude batteries)

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

Cuff circumference: approx. 22 ~ 42 cm (9" ~ 17")

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.
- 3. 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

AVITA BPM64R is intended for use in the electromagnetic environment specified below. The customer or the user of AVITA BPM64R must make sure that it is used in such an environment.

Guidance and manufacturer's declaration - Electromagnetic emissions		
Phenomenon	Professional healthcare	HOME HEALTHCARE
	facility environment a)	ENVIRONMENT a)
Conducted and radiated RF EMISSIONS	a)	CISPR 11 Group 1 Class B
Harmonic distortion	Not applicable	
Voltage fluctuations and flickering	Not applicable	

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

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

Phenomenon	Basic EMC	Immunity test levels	
		Professional	
	method	healthcare	ENVIRONMENT
		facility	
		environment	
ELECTROSTATIC	IEC 61000-4-2	± 8kV contact	
DISCHARGE		\pm 2 kV, \pm 4kV \pm , \pm 8 kV, \pm 15 kV air	
Radiated RF EM	IEC 61000-4-3	a)	10 V/m b) 80MHz - 2.7
fields			GHz 80% AM at 1kHz
Proximity fields	IEC 61000-4-3	COMPLIANT	
from RF wireless		NOTE: Further information about	
communications			be maintained between
equipment		portable and	
			ons equipment
			and the AVITA BPM64R
			sted from AViTA using the
			nation provided in this
			ever, it is advisable to
			tromechanical aerosol
			an adequate distance of,
		at least, 0.5 n	n from mobile phones or
			munications transmitters
			ossible interference.
RATED power	IEC 61000-4-8	30 A/m c)	
frequency		50 Hz or 60 H	łz
magnetic fields.	I		

- 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

[]i	Follow instructions 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
	"ON/OFF" (push-push)
†	Type of protection of applied part against electric shock, body floating
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°)
	Temperature limits
***	Manufacturer's name and address
SN	SN YYMWWWXXXXX SN: Product Serial Number YY: year, M:month, WWW: working sheet, XXXXX: serial no.



Manufacturer:
AViTA Corporation
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Sanchong Dist., New Taipei City,
Taiwan (R.O.C.)

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

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