

Wrist Type Blood Pressure Monitor

BPM27B

EN



IP 22

RoHS

REACH



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Importer



Distributor

INSTRUCTION MANUAL

Please read this instruction manual carefully before operating this unit

Contents

Intended Use.....	1
Important Information Before Use	5
Product Identification	8
Description of LCD Display	9
Battery Installation	10
Setting the Date and Time.....	12
Applying Your Cuff	14
Measurement of Pulse Rate and Blood Pressure	15
Hypertension Indicator	17
Irregular Heartbeat Detector.....	18
Memory Function	19
Data Transferring	22
Error Codes.....	26

Troubleshooting	27
Cleaning and Disinfecting.....	30
Technical Specification	31
EMC Tables.....	33
Explanation of Symbols.....	37

Intended Use

The product automatically measures human begins 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 arm. The intended use of this over-the-counter device is for adults with arm 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 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: ≤ 30 S Refer to IEC 80601-2-30
- No modification of this equipment is allowed.

Important Information Before Use

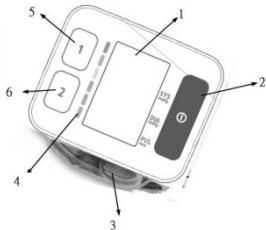
1. Blood pressure measurements should only be interpreted by a physician or a trained health care professional who is familiar with your medical history. Through regular use of this device and recording of your measurements, you can keep your physician informed of the changes in your blood pressure.
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, It is recommended that the accuracy should be checked by manufacture every 2 years. To obtain the service please contact AViTA Corp. for the address of the repair location. Enclose the Proof of Purchase. Include \$10.00 USD for the return shipping and handling. Include a letter, with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend insuring the product with return receipt requested. If in need of assistance of setting up, using, maintaining or to report unexpected operation/events please contact manufacturer or local representative for further information and assistance. Avoid the sensor degrading; it is needed calibrate the device every 2 year.

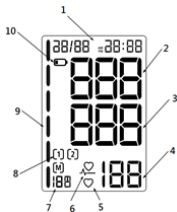
Product Identification



1. Display
2. ON/OFF button
3. Wrist Cuff
4. WHO Indicator
5. Memory 1 button, USER1
6. Memory 2 button, USER2


Description of LCD Display

1. Date and Time
2. Systolic Pressure
3. Diastolic Pressure
4. Pulse Value
5. Pulse Symbol 
6. Irregular Heart Beat Symbol 
7. Memory space number / memory display 
average value (A), morning (AM), evening (PM)
8. User memory [1] [2]
9. Classification of measurements
10. Low Battery Symbol 



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 ON/OFF button is pressed.

Replacing the Battery:

1. Press down on latch and lift the cover on the bottom of the monitor.
2. 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.
3. Replace 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.

Setting the Date and Time

This menu allows you to set the following functions, one after another.

It is essential to set the date and time. Otherwise, you will not be able to save your measured values correctly with a date and time and access them again later.

Hour format

- Press and hold the **ON/OFF** button  for 5 seconds.
- Select the desired hour format using the **USER1/USER2** memory buttons and confirm with the **ON/OFF** button .

Date

The year flashes on the display.

- Select the year using the **USER1/USER2** memory buttons and confirm with the **ON/OFF** button .

The month flashes on the display.

- Select the month using the **USER1/USER2** memory buttons and confirm with the **ON/OFF** button .

The day flashes on the display.

- Select the day using the **USER1/USER2** memory buttons and confirm with the **ON/OFF** button .

Noted: If the hour format is set as 12h, the day/month display sequence is reversed.

Time

The hours flash on the display.

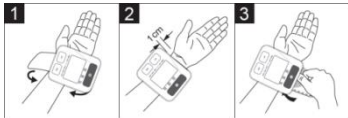
- Select the hour using the **USER1/USER2** memory buttons and confirm with the **ON/OFF** button .

The minutes flash on the display.

- Select the minutes using the **USER1/USER2** memory buttons and confirm with the **ON/OFF** button .

Once all the data has been set, the device switches off automatically.

Applying Your Cuff



Positioning cuff

- Bare your left Wrist, making sure that the circulation in the Wrist is not restricted by any clothes etc. That is too tight. Position the cuff on the inside of your Wrist.
- Fasten the cuff with the Velcro fastening so that the upper edge of the monitor is positioned approx. 1 cm below the ball of your thumb.
- The cuff has to be fitted tightly around the Wrist but should not constrict it.

Important:

The instrument should only be operated with the original cuff.



Measurement of Pulse Rate and Blood Pressure

Correct posture

- Rest for approx. 5 minutes before each measurement. Otherwise there may be divergences.
- You can perform the measurement while sitting or lying.
- To carry out a blood pressure measurement, make sure you are sitting comfortably with your Wrists and back leaning on something.
- Do not cross your legs. Place your feet flat on the ground.
- Make sure to relax your wrist and that the cuff is at heart level. Otherwise significant deviations may occur.
- In order not to distort the result, it is important to keep still during the measurement and not talk.

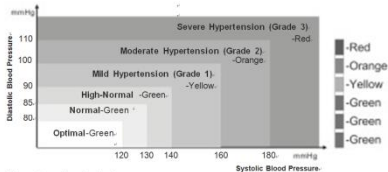


Measuring blood pressure

- Make sure to rest your arm and move it so that the device is at heart level as described previously.
- Press the ON/OFF button  to start the blood pressure monitor. All displays will illuminate briefly.
- The blood pressure monitor will begin the measurement automatically after 3 seconds. The measurement is taken during the inflation phase.
Noted: You can interrupt measurement at any time by pressing the  button.
- As soon as a pulse is found, the pulse symbol is displayed. The systolic pressure, diastolic pressure and pulse rate measurements are displayed.
- E_ appears if it has not been possible to perform the measurement properly. Observe the section in these instructions on error messages/troubleshooting and repeat the measurement.
- The test result is saved automatically.


Hypertension Indicator

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.



Hypertension Indicator.

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.

Memory Function

User memory

- The results of each successful measurement are stored together with date and time. With more than 100 items of measured data, the earliest items of data measured are lost.
- To recall measurements, press the memory button USER1 or USER2 . The device first shows the number of used memory spaces [1] [2] and then changes automatically to the average of all stored measurements \bar{A} .
- To view the measurements for user memory [1] press the USER1 memory button.
- To view the measurements for user memory [2] press the USER2 memory button.

Your last measurement will appear on the display.

Average Values

- Press the relevant memory button (USER1 or USER2).

Note:

Press the USER1 button if you have selected user memory 1. Press the USER2 memory button if you have selected user memory 2.

A appears on the display.

The average value of all saved measured values in this user memory is displayed.

- Press the relevant memory button (**USER1** or **USER2**). **AM** appears on the display. The average value of the morning measurements for the last 7 days is displayed. (morning: 5.00 a.m. – 9.00 a.m.).
- Press the relevant memory button (**USER1** or **USER2**). **PM** appears on the display. The average value of the evening measurements for the last 7 days is displayed (evening: 6.00 p.m. – 8.00 p.m.)
- Press the relevant memory button (**USER1** or **USER2**). **A** appears on the display.

The average value of last 3 measured values in this user memory is

displayed.

- By pressing the memory button **USER1** or **USER2** again, the most recent individual measurements are displayed with the date, time and graphic WHO classification, while the blood pressure values and the pulse are displayed in turn.
- In the display of the individual measured values, you have the option of clearing the memory by pressing the memory button **USER1** or **USER2** for 5 seconds. All values are deleted.

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) Download an app which supports Bluetooth GATT Service from iTunes App Store or Google Play.
- (2) Enable Bluetooth on your mobile device.
- (3) Open the app and activate the function.
- (4) Turn on the BPM27B.
- (5) The app should automatically detect your BPM27B. Tap the BPM27B that is showed in the device list.
- (6) Your BPM27B is now successfully connected to your mobile device. Every measure reading will be transfer to your mobile device automatically.
- (7) When the user connects with the mobile phone for the first time, user will need to scan enter the pairing device password on the

mobile phone, and the password will be displayed on the device's LCD ensure the security of the data transmission.

Note:

When connecting to the mobile phone for the first time, make sure that the pairing password is not leaked.

You can send results in memory zone as following step:

1. Press memory button (USER1 or USER2) of blood pressure monitor to enter memory mode. The symbol **(M)** and **A** will appear on the display.
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 button (USER1 or USER2) to display the memory result on LCD. Each result showed on LCD, the result will be transmitted by bluetooth

immediately.

Error Codes

In case of faults, the E_ message appears in the display. Error messages may appear if:

- It was not possible to record the pulse(E1 appears on the display),
- Inaccurate reading / movement(E2 appears on the display),
- The cuff is not fastened correctly(E3 appears on the display),
- Error occur during the measurements(E4 appears on the display),
- The pump pressure is higher than 300mmHg(E5 appears on the display),
- System error. Please contact customer service(E6 appears on the display),
- Battery is too low.(E7 appears on the display),

In the above cases, you must repeat the measurement. Reinsert the batteries if necessary, or else replace them.

Troubleshooting

Problem	Probable Cause	Recommended Action
Nothing appears in the display even when the power is turned on.	Batteries are drained.	Replace all batteries with new ones.
	Batteries are not correctly aligned with terminals.	Reinsert batteries in the correct position.
Low Battery Symbol appears.	Batteries are drained.	Replace all batteries with new ones.
	In colder temperatures batteries have weaker electrical charges.	Warm up the batteries, or use the device in a warmer setting.
Device operation time	Different battery brands have different life spans.	Use Alkaline batteries and replace all batteries at the

Problem	Probable Cause	Recommended Action
is inconsistent.		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.

Problem	Probable Cause	Recommended Action
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.

Cleaning and Disinfecting

- Clean your blood pressure monitor carefully using a slightly damp cloth only.
- Do not use any detergents or solvents.
- Never hold the instrument under water as otherwise liquid can penetrate and damage the instrument
- Never place any heavy objects on the instrument. Please note: For home use device disinfection, 75% Ethanol or Isopropyl alcohol(available in the phWristacy) can be used receipt requested.

Technical Specification

- Measuring range :
Blood Pressure : 30~280 mmHg
Pulse Rate : 40~199 beats/min
- Calibration Accuracy :
Pressure : ± 3 mmHg
Pulse rate : $\pm 4\%$ of reading
- Operating environment :
10°C~40°C (50°F~104°F)
with relative humidity up to 85% (non condensing)
Atmospheric Pressure: 700~1060 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 (Alkaline)

- Weight : approx. 115g (exclude batteries)
- Dimensions : approx. L 70 mm x W 85 mm x H 24 mm
- Cuff circumference : approx. 125~210 cm (4.9" ~ 8.3")
- Frequency : 2402~2480GHz
- Output power range : ≤ 4 dBm
- Life time: 3 years;
- Battery life: above 300 times

EMC Tables




<p>BPM27B is intended for use in the electromagnetic environment specified below. The customer or the user of BPM27B must make sure that it is used in such an environment.</p>		
<p>Guidance and manufacturer's declaration - Electromagnetic emissions</p>		
Phenomenon	<p>CISPR 11 Group 1 Class A (Not BLE Function) Group 2 Class A (With BLE Function)</p>	<p>CISPR 11 Group 1 Class B (Not BLE Function) Group 2 Class B (With BLE Function)</p>
Conducted and radiated RF EMISSIONS	<p>Not applicable (Note: Power by Battery or DC Input) Only the AC input needs to be tested</p>	
Harmonic distortion	<p>Not applicable (Note: Power by Battery or DC Input) Only the AC input needs to be tested</p>	
Voltage fluctuations	<p>CISPR 11</p>	


and flickering	Group 1 Class A (Not BLE Function) Group 2 Class A (With BLE Function)		
<p>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.</p> <p>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.</p>			
Guidance and manufacturer' s declaration - Electromagnetic immunity - Enclosure port			
Phenomenon	Basic EMC standard or test method	Immunity test levels	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT





ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8kV contact ± 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	<p>COMPLIANT</p> <p>NOTE: Further information about distances to be maintained between portable and mobile RF communications equipment (transmitters) and the BPM27B 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.</p>	




RATED power frequency magnetic fields.	IEC 61000-4-8	30 A/m c) 50 Hz or 60 Hz
<p>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.</p> <p>b) Before modulation is applied.</p> <p>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.</p>		



Explanation of Symbols



 <p>The CE marking consists of the letters 'C' and 'E' in a stylized font. Below the 'E' is the registration number '2797'.</p>	<p>The CE marking with the Registration Number of the Notified Body. This denotes the compliance of Regulation (EU) 2017/745</p>
 <p>The symbol 'MD' is enclosed in a square border.</p>	<p>Medical Device</p>
 <p>The symbol depicts a stylized industrial factory with three buildings of varying heights and a chimney.</p>	<p>Manufacturer</p>





<div data-bbox="100 180 293 239" style="border: 1px solid black; padding: 2px; display: inline-block;"> EC REP </div>	Authorized representative in the European Community
	Date of manufacture (YYYY-MM-DD or YYYY-MM)
<div data-bbox="135 498 258 570" style="border: 1px solid black; padding: 2px; display: inline-block;"> LOT </div>	Batch code (YMMWWWW)
<div data-bbox="135 660 253 733" style="border: 1px solid black; padding: 2px; display: inline-block;"> SN </div>	Serial number (YMWWWWXXXXX)

	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

	<p>Caution</p>
	<p>Consult the instruction for use</p>
	<p>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</p>
<p>RoHS</p>	<p>This product fulfilling the requirements of the RoHS Directive 2011/65/EU.</p>

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.
	"ON/OFF" (push-push)
	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 \varnothing and greater and against vertically falling water drops when enclosure tilted 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

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