

Wrist Type Blood Pressure Monitor

BPM11

EN



IP 22

RoHS

REACH



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Importer



Distributor

INSTRUCTION MANUAL

Please read this instruction manual carefully before operating this unit

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Intended Use

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

Contra-indications

- Please do not place the cuff over a wound as this may cause further injuries.
- If an intravenous treatment is being carried out or a venous catheter is inserted in the arm, blood pressure measurements can

lead to injury. Never use the cuff on the arm to which these conditions apply.

- If you are prone to hematoma, do not put on a cuff nor carry out a blood pressure measurement.

Consult your doctor before measuring your own blood pressure if...

- If you have any of the following conditions, it is essential you consult your doctor before using the device: cardiac arrhythmia, Cardiovascular disease, very low blood pressure, diabetes, circulatory problems, diabetes, liver function disorders or narrowing of blood vessels, blood disorders, pregnancy, pre-eclampsia, hypotension, chills, shaking, tremors, implanted electrical implants (e.g. pacemaker).
- You are on dialysis or taking anticoagulant medication (anticoagulants), platelet aggregation inhibitors or steroids.
- You tend to bruise easily and/or are sensitive to pressure pain.

Caution:

- Beware of blood flow interference and resulting harmful injury to the patient caused by continuous cuff pressure.
- Do not use the device at the same time as other medical electrical devices (ME equipment). This could lead to a malfunction of the device and/or an inaccurate measurement.
- Measurement results fundamentally depend on the measurement location and the position of the patient (sitting, standing, reclining). They are also influenced by e.g. physical activity and physiological preconditions of the patient. For comparable values, carry out the measurement in the same location and in the same position.
- Protect the device from impacts, humidity, dirt, marked temperature fluctuations and direct sunlight.
- Do not use the device outside of the specified storage and operating conditions. This could lead to incorrect measurements.
- Ensure the device is at room temperature before measuring. If the measuring device has been stored close to the maximum or

minimum storage and transport temperatures and is placed in an environment with a temperature of 20 °C, it is recommended that you wait approx. 2 hours before using the measuring device.

- Please note that when inflating the cuff, the functions of the limb in question may be impaired.
- During the blood pressure measurement, the blood circulation must not be stopped for an unnecessarily long time. If the device malfunctions remove the cuff from the arm.
- The blood pressure monitor is made from precision and electronic components. The accuracy of the measurements and service life of the device depend on its careful handling.
- Do not drop the device.
- Do not perform measurements more frequently than necessary. Due to the restriction of blood flow, some bruising may occur.
- 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.

- Do not use the cuff on people who have undergone a mastectomy.
- Do not place the cuff over wounds as this may cause further injury.
- High BMI health condition users may result varied.
- The blood pressure monitor must not be used in connection with a high-frequency surgical unit.
- Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.
- The measured values taken by you are for your information only - they are no substitute for a medical examination. Discuss the measured values with your doctor and never make your own medical decisions based on them (e.g. regarding dosages of medicines).
- The device is only intended for the purpose described in these instructions for use. The manufacturer is not liable for damage resulting from improper or incorrect use. No modification of this equipment is allowed.

- Users shall notify serious adverse event to the central competent authority or its commissioned agency, legal entity, or manufacture.
- If the irregular heart beat symbol appears often, it may indicate heart rhythm disorders. Please consult your doctor in that case. Severe heart rhythm disorders may sometimes produce lead to measurements or reduce the measurement accuracy. Please discuss with your doctor whether taking your own blood pressure is appropriate for you.

Important Information Before Use

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

2. Perform your measurement in a quiet place. You should be seated in a relaxed position.
3. Avoid smoking, eating, taking medication, alcohol consumption or physical activity 30 minutes prior to taking a reading. If you are exhibiting signs of stress, avoid taking your measurement until the feeling subsides.
4. Rest 15 minutes prior to taking a reading.
5. Remove any constrictive clothing or jewelry that may interfere with the cuff placement.
6. Keep the monitor stable during measurement to achieve an accurate reading. Remain still; do not talk during the measurement.
7. Record your daily blood pressure and pulse readings on a chart.
8. Take your readings at the same time, each day or as recommended

by your physician to get an accurate indication of change in your true blood pressure.

9. Wait a minimum of 15 minutes between readings to allow for the blood vessels to return to normal. The wait time may vary depending on your individual physiological characteristics.
10. Although such cases are rare, for those with an extremely weak pulse or irregular pulse, errors may result which prevent proper measurement. If abnormal variations are noticed, consult with your physician or trained healthcare professional.
11. This device is intended for adult use. While taking a measurement, you can stop the inflation or deflation process of the cuff at any time by pressing the POWER button.
12. If any serious incident that has occurred in relation to the device

should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

For Customer Service, the blood pressure monitor is calibrated when manufactured; it is recommended that the accuracy should be maintained and calibrated by manufacture triennially (every 3 years). To obtain the service please contact AViTA Corp. for the address of the repair location. Enclose with the Proof of Purchase. Include \$10.00 USD for the return shipping and handling. Accompany with a letter, with your name, address, phone number, and description of the specific problem or routine check-up. Pack the device carefully with bubble wraps (if there is) to prevent damages cause during transit. Due to possible losses in transit, it is recommended insuring the device with return receipt requested. If in any way of assistance of setting up, using, maintaining or to report unexpected operation/adverse events please contact manufacturer or local representative for further assistance.

Blood Pressure Monitor Features



Description of LCD Display



Memory sets



Memory Symbol



Average Measurement Symbol



Low Battery Symbol



Inflation Symbol



Deflation Symbol



Date

18:88^{AM}
PM

Time

888
288

Digital Display

188

Pulse Rate



Heartbeat Symbol



Hypertension Indicator



Irregular Heart Beat 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 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.
- Please properly dispose of the batteries away from small children

and heat.

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

Setting the Date and Time

It is 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 "M" 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.

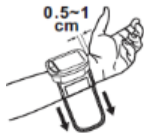
Applying Your Cuff

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

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



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



Measurement of Pulse Rate and Blood Pressure

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

- (1) Rest your elbow on a solid surface with your palm facing upward. Elevate your wrist so that the cuff is at the same level as your heart. Relax your left hand.
- (2) Press the POWER button. This will turn the power on.
- (3) After the self-test, the values for the last reading will appear on the display. The blood pressure monitor starts 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

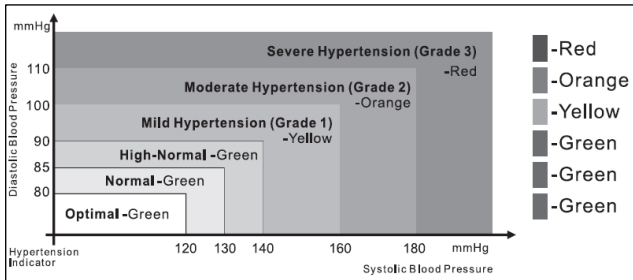


begin to show the decreasing pressure; the screen will display an arrow pointing down while you feel the pressure of the cuff decrease.

- (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. Select POWER to turn the unit off and conserve energy and battery life. The unit will automatically shut-off approximately 2 minutes.
- (10) The reading will automatically be stored in memory. Select POWER to turn the unit off and conserve energy and battery life. The unit will automatically shut-off approximately 2 minutes.

Hypertension Indicator

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



Irregular Heartbeat Detector

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

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

IMPORTANT INFORMATION:

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

Memory Function

Recalling Measurements in Memory:

- (1) Press and release the "M" button. The unit will first display the average of the last 3 stored measurements.
- (2) Continue to press the "M" button to successively view the next previously stored measurements. Measurements will appear on the display from most current to oldest; the memory number will appear on the lower right corner.

- (3) All results for a given measurement will display, including measurement results, pulse rate, Hypertension Indicator, and date/time stamp.
- (4) When the number of readings exceeds default numbers, 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.
- (6)


Clearing Measurements from Memory:

From power display off, press and hold down the "M" button until the display shows CLr. This indicates that all measurements have been erased.



Error Codes

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

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

Troubleshooting

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

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

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



Cleaning and Disinfecting

- Only use a soft, damp cloth to clean the monitor. Please do not use thinner, alcohol, detergents or solvents.
- The cuff can be cleaned carefully using a slightly damp cloth and mild soap solution. Do not completely immerse the cuff in water.
- It is recommended to clean and disinfect the cuff regularly or after each use, especially when used by several users, to prevent infection. The cuff should be disinfected, particularly on the inside, by wiping with

a disinfectant. Use a disinfectant that is compatible with the cuff materials, e.g. 75 % ethanol or isopropyl alcohol.

- Keep the monitor in the appropriate carriage to protect it from external influences. And store it at appropriate condition.

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

- Weight : approx. 120g (exclude batteries)
- Dimensions : approx. 71mm × 84mm × 32.2mm (L×W×H)
- Cuff circumference : approx. 12.5~21 cm
- Lifetime : 3 years
- Battery life: above 300 times

EMC Tables

<p>BPM11 is intended for use in the electromagnetic environment specified below. The customer or the user of BPM11 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 and flickering	<p>CISPR 11 Group 1 Class A (Not BLE Function)</p>	

	Group 2 Class A (With BLE Function)
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- 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 standard or test method	Immunity test levels	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC	IEC 61000-4-2	± 8kV contact	





DISCHARGE		$\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 8 \text{ kV}, \pm 15 \text{ kV}$ 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 BPM11 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.</p>	
RATED power frequency	IEC 61000-4-8	30 A/m c) 50 Hz or 60 Hz	




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



Explanation of Symbols



Symbol	Definition
 The image shows the CE marking, which consists of the letters 'C' and 'E' in a stylized font. Below the 'E' is the number '2797'.	The CE marking with the Registration Number of the Notified Body. This denotes the compliance of Regulation (EU) 2017/745
 The image shows the letters 'MD' enclosed in a rectangular box.	Medical Device
 The image shows a stylized silhouette of a factory with three buildings of varying heights.	Manufacturer





<div data-bbox="100 189 293 246" style="border: 1px solid black; padding: 2px; display: inline-block;"> EC REP </div>	<p>Authorized representative in the European Community</p>
	<p>Date of manufacture (YYYY-MM-DD or YYYY-MM)</p>
<div data-bbox="132 534 261 614" style="border: 1px solid black; padding: 2px; display: inline-block;"> LOT </div>	<p>Batch code (YYMMWWWW)</p>
<div data-bbox="135 715 258 795" style="border: 1px solid black; padding: 2px; display: inline-block;"> SN </div>	<p>Serial number (YYMWWWWXXXXX)</p>

	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

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

<p>REACH</p>	<p>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.</p>
	<p>Stand-by</p>
	<p>Device classification type BF</p>

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



Keep away from sunlight

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

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