

Wrist Type Blood Pressure Monitor

BPM28

EN



IP 22

RoHS

REACH

EC REP

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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 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

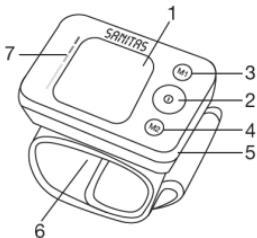
authority of the Member State in which the user is established.

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

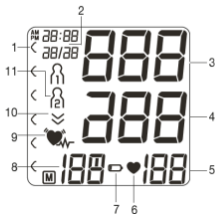
Blood pressure monitor and cuff:

1. Display
2. **START/STOP** button ⓘ
3. Memory button **M1**
4. Memory button **M2**
5. Battery compartment lid
6. Wrist cuff
7. Risk indicator



Description of LCD Display

1. Risk indicator
2. Time and date
3. Systolic pressure
4. Diastolic pressure
5. Calculated pulse rate
6. Pulse symbol ♥
7. Battery indicator 🔋
8. Memory space number/memory display for average value (R), morning (Rf), evening (Pf)
9. Cardiac arrhythmia symbol ♥_W
10. Release air ⇩
11. User memory 👤 / 👤



Battery Installation

Inserting the batteries

- Remove the battery compartment lid on the right side of the device.
- Insert two 1.5 V AAA micro (alkaline type LR03) batteries. Make sure that the batteries are inserted the correct way round in accordance with the markings. Do not use rechargeable batteries.
- Close the battery compartment lid again carefully.
- All display elements are briefly displayed, flashes on the display. Now make the settings as described below.

If the battery replacement symbol flashes, you can no longer perform any measurements and must replace all batteries. Once the batteries have been removed from the device, the date and time must be set again. Any saved measured values are retained.

Setting the Date and Time

You must make sure that the device has the correct settings before use in order to be able to make full use of all functions. Only by doing so can your measurements with associated date and time be saved and accessed later by you.

There are two different ways to access the menu from which you can adjust the settings:

- Before initial use and after each time you replace the battery:

When inserting batteries into the device, you will be taken to the relevant menu automatically.

- If the batteries have already been inserted:

With the device switched off press and hold the START/STOP button for approx. 5 seconds.

In this menu you can adjust the following settings in succession:

Hour format



Date



Time

Hour format

The hour format flashes on the display.

- Select the desired hour format using the **M1** or **M2** memory button and confirm with the **START/STOP** button **⓪**.



Date

The year flashes on the display.

- Select the desired year using the memory button **M1** or **M2** and confirm with the **START/STOP** button **⓪**.



The month flashes on the display.

- Select the desired month with the memory button **M1** or **M2** and confirm with the **START/STOP** button **⓪**.



Date

The day flashes on the display.

- Select the desired day using the memory button **M1** or **M2** and confirm with the **START/STOP** button **⓪**.



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

Time

The hours flash on the display.

- Select the desired hour using the memory button **M1** or **M2** and confirm with the **START/STOP** button **⓪**.



The minutes flash on the display.

- Select the desired minute using the memory button **M1** or **M2** and confirm with the **START/STOP** button **⓪**.



The device then switches itself off automatically.

Applying Your Cuff

General rules when measuring blood pressure yourself

- In order to generate as informative a profile of the progression of your blood pressure as possible and ensure that the measured values can be compared, you should measure your blood pressure regularly and always at the same times of day. It is recommended that you measure your blood pressure twice a day: once in the morning after getting up and once in the evening.
- You should always carry out the measurement when you are sufficiently physically rested. You should therefore avoid taking measurements during stressful periods.
- Do not take a measurement within 30 minutes of eating, drinking, smoking or exercising.
- Before the initial blood pressure measurement, make sure always to rest for about 5 minutes.
- Furthermore, if you want to take several measurements in succession,

make sure always to wait for at least 1 minute between the individual measurements.

- Repeat the measurement if you are unsure of the measured value.

Attaching the cuff

- Fundamentally, blood pressure can be measured on both arms. Certain deviations between the measured blood pressure on the right arm and left arm are due to physiological causes and completely normal. You should always perform the measurement on the arm with the highest blood pressure values. Before starting self-measurement, consult your doctor in this regard. From this point on, always take measurements on the same arm.
- The device may only be operated with the cuff attached when supplied. Before using the device, the user should check the fit of the cuff and, in doing so, ensure that their wrist circumference is within the range printed on the cuff.
- Uncover your wrist. Ensure that the circulation of the arm is not hindered by tight clothing or similar.

- Now place the cuff on the wrist so that the palm of your hand and the device display are facing upwards.
- Position the cuff so that there is a distance of 1.0 – 1.5 cm between it and the heel of your hand.
- Now fasten the cuff tightly around your wrist using the hook-and-loop fastener. Make sure that it is tight but that it does not cut into your wrist.

Adopting the correct posture

- To carry out a blood pressure measurement, make sure you are sitting upright and comfortably. Lean back and place your arm on a surface. Do not cross your legs. Place your feet next to each other flat on the floor.
- Always make sure that the device is at heart level during the measurement. Otherwise significant measurement deviations can occur due to physiological causes. To do so, place your elbow on a

table to support your arm. In order to make the measurement even more comfortable for you, you can place your lower arm on a suitable object (e.g. the storage box).

- Relax your arm and the palm of your hand.
- To avoid distorting the measurement, you should remain as still as possible during the measurement and not speak.

Measurement of Pulse Rate and Blood Pressure

Selecting the user

This device has 2 user memories with 100 memory spaces each in order that you can save measurements from 2 different people separately from each other.

If multiple people are using the device, make sure that the relevant user is set before each measurement.

To select the relevant user memory, press the memory button M1 (for user) or M2 (for user memory) when the device is switched off. Then confirm your selection by pressing the START/STOP button .

Performing the blood pressure measurement

- Press the START/STOP button to start the blood pressure monitor. All display elements are briefly displayed.
- The blood pressure monitor will begin the measurement

automatically after approx. 3 seconds.

- The cuff inflates automatically while the actual measuring process starts. As soon as a pulse is found, the pulse symbol is displayed. You can cancel the measurement at any time by pressing the START/STOP button
- The remaining air is released quickly once the measurement is complete.
- Systolic pressure, diastolic pressure and pulse measurements are displayed.
- appears if the measurement could not be performed properly. In this case, please read the section " What if there are problems?" .
- Press the START/STOP button to switch off the blood pressure monitor. The measurement is then stored in the selected user memory.

Evaluating the results

General information about blood pressure

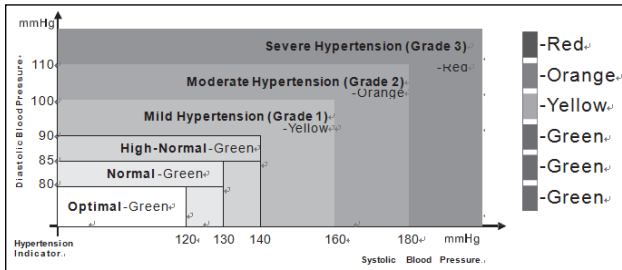
- Blood pressure is the force with which the bloodstream presses

against the arterial walls. Arterial blood pressure constantly changes in the course of a cardiac cycle.

- Blood pressure is always stated in the form of two values:
 - The highest pressure in the cycle is called systolic blood pressure. This arises when the heart muscle contracts and blood is pumped into the blood vessels.
 - The lowest is diastolic blood pressure, which is when the heart muscle has completely stretched back out and the heart fills with blood.
- Fluctuations in blood pressure are normal. Even during repeat measurements, considerable differences between the measured values may occur. One-off or irregular measurements therefore do not provide reliable information about the actual blood pressure. Reliable assessment is only possible when you perform the measurement regularly under comparable conditions.

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

Saving, accessing and deleting measured values

User memory

The results of every successful measurement are stored together with the date and time. The oldest measurement is overwritten in the event of more than 100 measurements.

- To select the relevant user memory, press the memory button **M1** (for user ) or **M2** (for user memory ) when the device is switched off. Then confirm your selection by pressing the **START/STOP** button .

R flashes on the display.

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

- Press the memory button **M1**.

R^m flashes on the display.

The average value of the morning measurements for the last 7 days is displayed (morning: 5 a.m. – 9 a.m.).

- Press the memory button **M1**.

P^m flashes on the display.

The average value of the evening measurements for the last 7 days is displayed (evening: 6 p.m. – 8 p.m.).

- When you press the memory button **M1** again, the last individual measurement is displayed (in this example, measurement 03).
 - When you press the memory button **M1** again, you can view your individual measurements.
 - To switch the device off again, press the **START/STOP** button ①.
- ① You can exit the menu at any time by pressing the **START/STOP** button ①.

- In order to delete a user memory, first select the user memory to be deleted by pressing the memory button **M1** or **M2** when the device is switched off and confirming your selection by pressing the **START/STOP** button ①.
- The average value of all measurements for the selected user memory appears on the display; at the same time R flashes on the display.
- Now press and hold the memory buttons **M1** and **M2** at the same time for 5 seconds. **CL 00** appears in the display. All the values in the selected user memory have now been deleted.



Error Codes

Error message	Possible cause	Solution
Err00	Unable to record a pulse.	Please wait one minute and repeat the measurement. Ensure that you do not speak or move during the measurement.
Err01	An error occurred while inflating the cuff or the inflation pressure is over 300 mmHg.	Please take another measurement to check whether the cuff can be correctly inflated. Please observe the information in chapter "Attaching the cuff" in particular.
Err02	The measured blood pressure is outside the measurement range.	Please wait one minute and repeat the measurement.
Err03	An error occurred during the measurement.	Ensure that you do not speak or move during the measurement.
Err	System error	Please contact Customer Services.
0	The batteries are almost empty.	Insert new batteries into the device.

If the problem still occurs despite the suggested corrective actions, please contact Customer Services.

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

- 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

- Weight : approx. 105g (exclude batteries)
- Dimensions : approx. L 85 mm x W 60 mm x H 22 mm
- Cuff circumference : approx. 125~210 cm
- Life time: 3 years
- Battery life: above 300 times

EMC Tables

<p>BPM28 is intended for use in the electromagnetic environment specified below. The customer or the user of BPM28 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 BPM28 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	IEC 61000-4-8	30 A/m c)	




frequency magnetic fields.		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>CE 2797</p>	The CE marking with the Registration Number of the Notified Body. This denotes the compliance of Regulation (EU) 2017/745
 <p>MD</p>	Medical Device
 <p>Manufacturer</p>	Manufacturer





EC REP	Authorized representative in the European Community
	Date of manufacture (YYYY-MM-DD or YYYY-MM)
LOT	Batch code (YMMWWWW)
SN	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

<p>IP 22</p>	<p>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°)</p>
	<p>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.</p>
	<p>Importer</p>

	Distributor
	Model Number
	Country of Manufacturer
	Unique Device Identifier

*BPM28P-22008AV
2022-12-14*