Wellex

Arm Type Blood Pressure Monitor

Model: BPM83

INSTRUCTION MANUAL

Please read this instruction manual carefully
before operating this unit.

Contents

Intended Use

The BPM83 Series 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 220 mm to 420 mm (Approx. 8.7 ~ 16.6 inches) and for home use. When the device detects the appearance of irregular heartbeats such as atrial or ventricular premature beats during measurement, an indicated symbol will appear with measuring readings.

This device is designed only for adults.

Important Information Before Use

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

Important Information Before Use

For Customer Service, It is recommended that the accuracy should be checked by manufacture every 1 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 1 year.

- Clinical accuracy and the protocols for investigating the clinical accuracy meet ISO 81060-2:2013.
- Do not use in this case. (e.g. Device for use in an ambulance or helicopter, For use in the professional environment.)
- This product is suitable for use in the home healthcare environment.
- The performance of the device can be affected by extremes of temperature, humidity and altitude, Please refer to the instructions for use.

CAUTION:

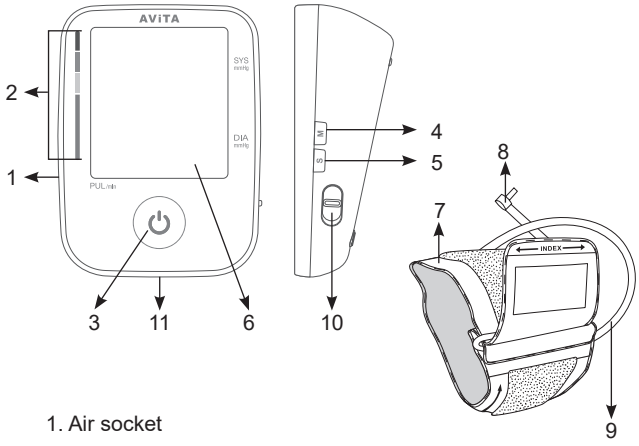
Keep this device out of the reach of children. Strangulation resulting from baby or child entanglement in cables.

Please keep this device away from pets, pests, and children.

Avoid potential allergic reactions, please avoid the device in direct contact to patient's wound.

• WARNING: No modification of this equipment is allowed.

Product Identification



1. Air socket
2. WHO Indicator
3. Start/Stop button (Power key)
4. Memory button (M key)
5. Set button (S key)
6. Display
7. Cuff
8. Cuff connector
9. Cuff tube

10 Atrial Fibrillation Detection (AFIB) model (Optional)

11 USB Type C Socket (Optional)

Description of LCD Display

	Low battery indicator
	WHO indicator
	Date & Time
	Irregular Heartbeat Symbol
	AF Symbol
	Memory Symbol
	Memory Set
	Heartbeat Symbol
	Pulse rate
	Release air
	Systolic Pressure
	Diastolic Pressure

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 key is pressed.

Replacing the Battery:

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

CAUTION:

Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.

AC Power Adapter(NOT Incuded)

Type: 

Input:AC 100~240V 50/60HZ

Output:DC5V 1.0A

NOTE: Battery-operated

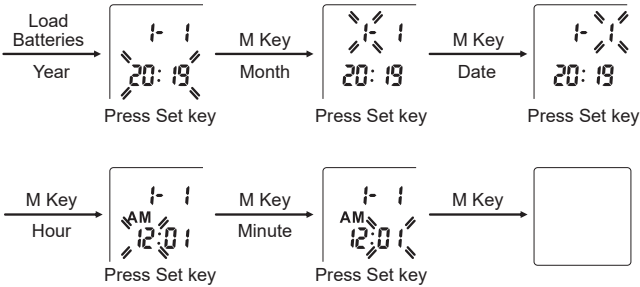
1. Please properly dispose of the batteries away from small children and heat. Avoid the children accidentally swallow the battery.
2. It is recommended to remove the batteries if the unit will not be used for more than 1 month.
3. Batteries must be disposed of in accordance with local environmental and institutional policies.

Setting the Date and Time

It is necessary to set the date and time for the unit every time batteries are initially installed or replaced.

To set the date and time, proceed as follows:

- While in power off mode, press and hold the “SET” key for at least 3 seconds to enter Date and Time setting procedure and the Year value will begin to flash.
- Press the “SET” key to advance the display to the desired year, press the “M” key to confirm the year.
- Next, the month will blink. Repeat step 2 to set the month and date, then hours, then minutes.
- After setting the minutes, the unit will automatically exit out of the date/time setting mode and shut off.



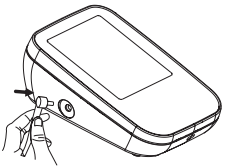
Placement of the Pressure Sleeve

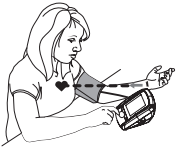
It is important to avoid smoking, eating, taking medication, alcohol consumption or physical activity 30 minutes prior to taking a reading. If for any reason you are unable to or should not use your left arm, please modify the instructions for cuff application to your right arm. Your physician can help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

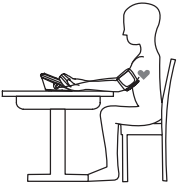
1. Remove any constrictive clothing or jewelry that may interfere with cuff placement.
2. Be seated at a table or desk with your feet flat on the floor.
3. The cuff should not be plugged into the monitor until after the cuff is applied to your arm.

Note:

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



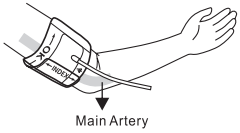




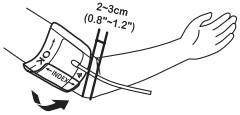
4. Position the cuff on a solid surface with the tubing facing up and away from you. The metal ring/bar on the cuff should be to the left of the tubing.
5. Open the cuff by pulling or rolling the bottom of the cuff to the right. This should open the

cuff without fully unrolling it, creating a cylinder. Do not fully unwrap or unroll the cuff.

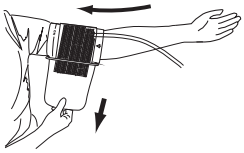
6. Insert your left arm into the created cuff cylinder. Position the (⍒) mark over the main artery on the inside of your arm.



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



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



9. The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger easily between your arm and

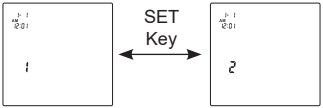
Note:

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

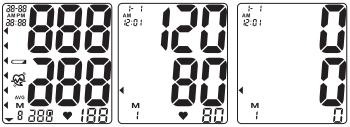
Measurement of Pulse Rate and Blood Pressure

To set the user and memory zone, proceed as follows:

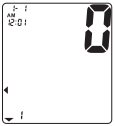
While in power off mode, press the “SET” key to select user. Confirm your selection with the Power key to turn the power on and start to measure your blood pressure. Or wait for 3 seconds, your selection is then stored and shut off automatically.



1. Press the Power key to turn the power on. After full display is shown, the values for the last reading will appear on the display. If there is no measurement, the unit displays the value “0”.



2. After the self-test, the blood pressure monitor starts to measure. The cuff will automatically begin to inflate, with the display showing the increasing pressure in the cuff.
3. As the pressure increases, the indicator will increase upwards according to the pressure value on the display.
4. As the cuff inflates, the monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation.



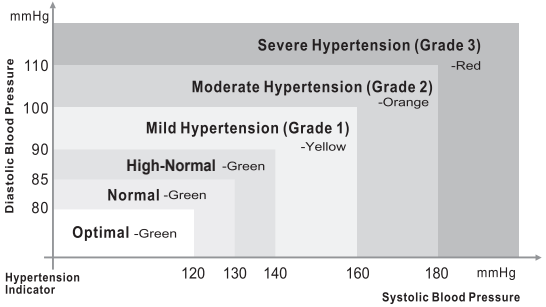
Measurement of Pulse Rate and Blood Pressure

5. To detect the heartbeat, the heartbeat symbol will appear and continuous flashes on the LCD display.
6. Your blood pressure measurement and pulse will display simultaneously on the screen.
7. The Hypertension Indicator will indicate your reading range on the display separately.
8. Press the Power key to turn the unit off and conserve energy and battery life.

   The unit will automatically shut-off approximately 2 minutes.

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.



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:

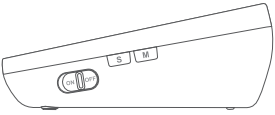
Please consult with your physician or trained healthcare professional for further information regarding an atrial fibrillation and if this symbol appears frequently.

Atrial Fibrillation (AFIB)

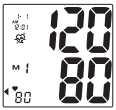
This device is a blood pressure monitor that also analyses heart rate variability during measurement.

While in power off mode, switch the “AF” key to select AF mode “ON” or “OFF”. After measurement mode setting, press the “SET” key to select user. Confirm your selection with the Power key to turn the power on and start to measure your blood pressure. Or wait for 3 seconds, your selection is then stored and shut off automatically.

This feature allows users to accurately monitor blood pressure even



if atrial fibrillation should occur. When atrial fibrillation is detected, the “ AF ”icon will appear on the display.



Note:

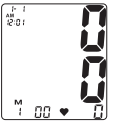
Please consult with your physician or trained healthcare professional for further information regarding an atrial fibrillation and if this symbol appears frequently.

Memory Function

Recalling Measurements in Memory:

You can recall up to 100 measurements for each user, plus those average values stored measurements in memory to share with your physician or trained healthcare professional.

If you press the M key, the unit will first display the average of last 3 currently stored measurements. Continue to press the M key to successively view the average value of the morning measurements and evening measurements for the last 7 days will be displayed.



The duration of morning is AM5:00 – AM9:00,

The duration of evening is PM6:00 – PM8:00

If you press the M key again, the measurements will appear on the display from most current to oldest. And the memory number will appear on the display.

All results for a given measurement will display, including measurement results, pulse rate, Hypertension Indicator, Irregular Heartbeat alert, and date/time stamp.

When the number of readings exceeds 100, the oldest data will be replaced with the new record.

Press the Power key to turn the unit off at any time when you check the stored measurements

Memory Function

Clearing Measurements from Memory:

From the memory mode, press and hold down the M key until the display shows CLr. This indicates that all measurements have been erased.

Error Codes

Err Code	Meaning	Corrective Action
Err 00	No pulse or detect pulses not enough.	Take off heavy clothes and retry again.
Err 01	The cuff is not fastened correctly	The Arm cuff is not fastened properly. Re- apply the cuff, and take a measurement again.
Err 02	Inaccurate reading	Rest a while, relax and retry again.
Err 03	Inflation or deflation fail during the measurement	The Arm cuff is not fastened properly. Re- apply 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.

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.
	Battery 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 is inconsistent.	Different battery brands have different life spans.	Use Alkaline batteries and replace all batteries at the same time with same brand batteries.
No reading after measurement.	Batteries are drained.	Replace all batteries with new ones.
Suspicious blood pressure results.	Perhaps the cuff was improperly positioned.	Adjust patient and arm cuff to measure.
	Blood pressure naturally varies throughout the day.	Rest a while, relax and measure again.
Suspicious heart rate results.	Bodily movement during device use.	Refrain from moving during measurement.
	Measurement shortly after exercise or exposure to the outdoors.	Do not take measurements after exercise or coming back from the outdoors.
Power switches off automatically.	System design.	Push the power button again, and then begin measure again.
During measuring, air re-inflates.	It could be a normal action if the user's blood pressure is higher than the initial pressure value, the device automatically pumps to a higher pressure by 40mmHg each time.	Relax, and try to take a measure again.
	The arm cuff is not fastened properly.	Check that the arm cuff is fastened properly and retake the measurement.

Care and Maintenance

- 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.

We provide a 2-year warranty covering faults in materials or manufacture of the product from the purchase date. The warranty does not cover:

- Damage resulting from improper use.
- Wear parts.
- Defects that were known to the customer at the time of purchase.
- Damage for which the customer was responsible.

This warranty does not affect the customer's legal rights. The customer must provide proof of purchase in order for any warranty claims within the warranty period to be honoured. Claims under the warranty within a period of 2 years from the date of purchase are honoured by MDSS GmbH., Schiffgraben 41, 30175 Hannover, Germany.

In the event of a warranty claim, the customer has the right to have the goods repaired by our own work- shop or a workshop authorized by use. The device must not be opened for any reason. Opening or modifying the device invalidates the warranty. This warranty does not grant any additional rights to the customer.

Care and Maintenance

Please note: It is recommended that the accuracy should be checked by manufacture every 1 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.

Applied Standards

- This unit is in line with European Standard EN 60601-1-2 and is subject to particular precautions with regard to electromagnetic compatibility (EMC). Please note that portable and mobile HF communication systems may interfere with this unit. More details can be requested from the stated Customer Service address or found at the end of the instructions for use.
- This device is in line with the EU Medical Devices Directive 93/42/ EC, the “Medizinproduktegesetz” (German Medical Devices Act) and EN 1060-3 (non-invasive sphygmomanometers, Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems) and IEC 80601-2-30 (Medical electrical equipment – Part 2 – 30: Particular requirements for the safety and essential performance of automated non-invasive blood pressure monitors).
- The accuracy of this blood pressure monitor has been carefully checked and developed with regard to a long useful life. If using the device for commercial medical purposes, it must be regularly tested for accuracy by appropriate means. Precise instructions for checking accuracy may be requested from the service address.

Technical Specification

- Measuring range :
  Blood Pressure : 40~255 mmHg
  Pulse Rate : 40~199 beats/min
- Calibration Accuracy :
  Blood Pressure : ± 3 mmHg
  Pulse rate : ± 4% of reading
- Operating environment :10ºC~40ºC
  ≤ 85 % relative air humidity (non-condensing) ,
  700-1060 hPa ambient pressure

- Storage/ Transportation environment : -20ºC~+50ºC
  ≤85 % relative air humidity (non-condensing),
  700-1060 hPa ambient pressure
  with relative humidity up to 85% (non condensing)

- Power Source : 4 x 1.5 V AAA batteries
- Weight : approx. 222g (exclude batteries) +/- 5%
- Dimensions : approx. L 138 mm x W 103 mm x H 54 mm
- Cuff circumference (M/L Size) : approx. 22 ~ 42 cm (9” ~ 17”)

EMC Tables

AViTA BPM83 is intended for use in the electromagnetic environment specified below. The customer or the user of **AViTA BPM83** must make sure that it is used in such an environment.

Guidance and manufacturer's declaration - Electromagnetic emissions

Phenomenon	**Professional healthcare facility environment a)**	**HOME HEALTHCARE 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 standard or test method	mmunity 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	COMPLIANT NOTE: Further information about distances to be maintained between portable and mobile RF communications equipment (transmitters) and the AViTA BPM83 can be requested from AViTA 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.	
RATED power frequency magnetic fields.	IEC 61000-4-8	30 A/m c) 50 Hz or 60 Hz	

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

CE 0598	The CE marking with the Registration Number of the Notified Body. This denotes the compliance of European Medical Device Directive 93/42/EEC
MD	Medical Device
	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
	Stand by
	Device classification type BF
IP22	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
	Humidity limits
EC REP	European Authorized Representative
	Manufacturer's name and address
	Date of manufacture
----	Direct current
SN	SN YYMWWWXXXXX SN: Product Serial Number YY: year, M:month, WWW: working sheet, XXXXX: serial no.
LOT	LOT WWWXXXXX LOT: Lot Number WWW: working sheet, XXXXX: serial no.
RoHS	This product fulfilling the requirements of the RoHS Directive 2011/65/EU.
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.

EC REP MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany

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

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

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