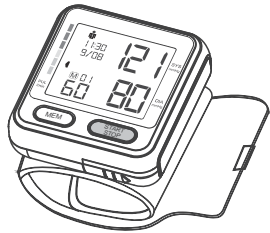




## Wrist Blood Pressure Monitor



With a color coded alert system, this device screen shows green when it detects normal blood pressure, yellow if you are at risk of developing high blood pressure, and red for high blood pressure.

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### 1. Before Using This Device

#### 1.1 Indications For Use

This wrist blood pressure monitor is intended to be used to measure blood pressure and pulse rate from the wrist by using the oscillometric method, at home.

This device is intended for use on adults only and is not for use on neonatal babies, children, pregnant women, or pre-eclamptic patients.

#### 1.2 Important Safety Information and Precautions

**MEDICAL DISCLAIMER:** This device and manual are not meant to be a substitute for advice provided by doctors or other medical professionals. Contact your physician for interpretation of measurements, or if you have or suspect you have a medical issue.

#### WARNING

- Contact your physician if you suspect you have a medical issue.
- Not for use by children, pregnant women, or pre-eclamptic patients.
- If you suffer from arrhythmia, diabetes, blood circulation problems, or apoplexy, only use this device under a physician's care.
- Prolonged over-inflation of the monitor will result in harmful injury to the patient.
- Do not use this device over a wound, as this can cause further injury.
- Too frequent measurements can cause injury due to blood flow interference.
- This device possible cause improper result due to external interference, such as acceleration during transport or transport in general.
- Do not attempt to modify this device in any way.
- Store this device in a cool, dry place. Do not subject this device to extreme temperatures, humidity, or sunlight. This device might not meet performance specifications if stored or used outside the ranges specified in the "Specifications" section. Keep away from rain.
- Do not immerse this device in water or clean with cleaning products, alcohol, or solvents. Carefully follow cleaning instructions provided.
- Remove batteries if this device will not be used for three or more months.
- Ensure that the device is used in the environment specified in the EMC declaration in this IM, otherwise, may result in improper operation.
- Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation.
- This electrical medical equipment requires specific precautions regarding electromagnetic compatibility. It must be installed and used according to the electromagnetic information.
- Do not use this device where flammable gases or liquids are present.
- Never drop the device.

Technical description is contained in this instruction manual.



KEEP BATTERIES AND BATTERY DOOR AWAY FROM CHILDREN. HARMFUL IF SWALLOWED.



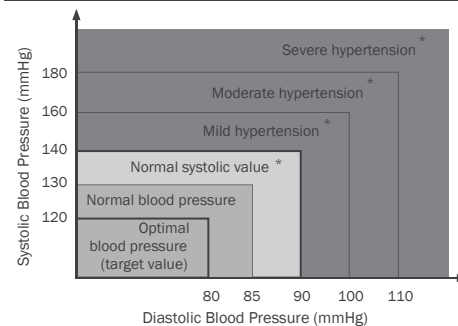
DO NOT MIX OLD AND NEW BATTERIES. REPLACE BATTERIES WITH A NEW SET IF A LOW BATTERY SYMBOL APPEARS ON DISPLAY. DO NOT USE RECHARGEABLE BATTERIES. DO NOT MIX ALKALINE, STANDARD (CARBON-ZINC) OR RECHARGEABLE (NICKEL-CADMIUM) BATTERIES. REMOVE BATTERIES IF THE DEVICE IS NOT IN USE FOR A PERIOD OF THREE MONTHS OR MORE.



PLEASE READ THIS INSTRUCTION MANUAL THOROUGHLY BEFORE USING THE UNIT. PLEASE KEEP FOR FUTURE REFERENCE.

#### 1.3 About Blood Pressure

**BLOOD PRESSURE INDICATOR CHART**  
(World Health Organization (WHO) Blood Pressure Indicator)

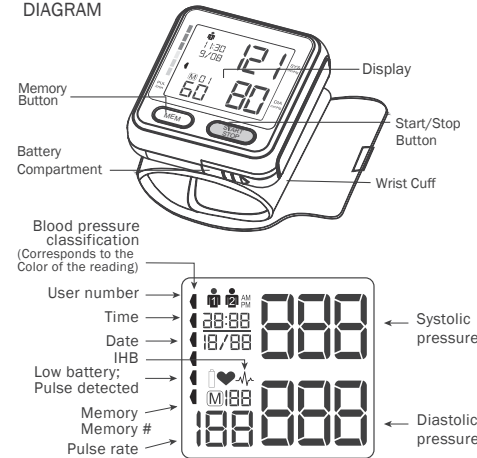


When systolic and diastolic pressure cross into different categories, the higher pressure value determines the color code.

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults. An irregular heartbeat (IHB) rhythm is defined as a rhythm that is more than 25% slower or 25% faster from the average rhythm detected while the device is measuring the systolic blood pressure and the diastolic blood pressure. When the device detects an irregular rhythm two or more times during the measurement, the Irregular Heartbeat Symbol will be displayed with the measurement values.

### 2. Setting Up

#### 2.1 Getting to Know Your Device DIAGRAM



#### 2.2 How to Set Up Your Device

##### Battery Installation:

- Slide open the battery cover, located on left side of this device. (Figure 1)
- Insert two AAA alkaline batteries according to the + and - markings. (Figure 2)
- Slide the battery cover back into place, ensuring that it clicks into place. Make sure that the battery cover is securely in position.

Figure 1



Figure 2



**NOTE:** When the low battery symbol appears on screen, turn off this device and follow these instructions

#### CAUTION

Never leave any low battery in the battery compartment as it may leak and cause damage to this device.

#### 2.3 Setting of User, Year, Date, Time

- If device is already on immediately after battery installation, toggle between User 1 and User 2 by pressing "START/STOP" button. If device is turned off, press and hold "MEM" button for 2 seconds, then toggle between User 1 and User 2 by pressing "START/STOP" button. To select user, press "MEM" to confirm and then flashing year digits occur.

- Press "START/STOP" to increase one year or press and hold "START/STOP" to increase several. Press "MEM" to confirm and then flashing month digits occur.
- Press "START/STOP" to increase one month or press and hold "START/STOP" to increase several. Press "MEM" to confirm and then flashing day digits occur.
- Press "START/STOP" to increase one day or press and hold "START/STOP" to increase several. Press "MEM" to confirm and then flashing hour digits occur.
- Press "START/STOP" to increase one hour or press and hold "START/STOP" to increase several. Press "MEM" to confirm and then flashing minute digits occur.
- Press "START/STOP" to increase one minute or press and hold "START/STOP" to increase several. Press "MEM" to confirm and then the device turns off.
- Setting is completed.

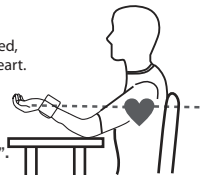
### 3. Instructions For Use

#### 3.1 Before Taking a Measurement

- For most accurate results, measurements should be taken under similar circumstances and at the same time every day
- This device can be applied to either wrist, but preferably the left. Use the same wrist for each measurement.
- Any blood pressure recording may be affected by the position and physiological condition of the subject, as well as other factors such as background noise, stress, talking and body movement etc.
- Avoid taking measurements while under stress.
- Do not eat, drink alcohol, smoke, exercise, or bathe 30 minutes before using this device, as these activities may change blood pressure.
- For an accurate indication of true blood pressure, take and record several measurements over a period of time.
- If consecutive measurements are desired, allow two minutes between uses to allow blood to flow through the arm normally.
- This device is used to monitor blood pressure. However, it cannot treat or prevent high blood pressure. If you suffer from high blood pressure, consult your doctor. Self-diagnosis and treatment using readings may be dangerous. Follow the instructions of your physician or licensed healthcare provider.

#### 3.2 Measurement

- This device should be used on bare skin. Remove wristwatches or other jewelry. If necessary, loosely roll up your sleeve to expose wrist.
- With screen aligned to the midline of your palm and facing towards you, wrap the cuff around your wrist. Secure this device cuff firmly by attaching velcro fastener.
- Comfortably sit down near a table or place to rest your arm
  - Keep your legs uncrossed
  - Place your feet flat on the floor
  - Preferably have your back and arm supported,
  - Keep the device at the same level as your heart.
  - Relax as much as possible and do not talk during the measurement.



- While sitting upright in a chair with your feet flat on the floor, press "START/STOP". Symbols on screen will flash and cuff will begin to inflate. Do not move, activate arm muscles, or talk during measurement.

#### 5. Measurement can be stopped at any time by pressing "START/STOP".

- When this device senses a pulse, a heart symbol will flash on screen.
- When measurement is complete, the cuff deflates automatically and your systolic, diastolic, and pulse rate will display on screen.
- The screen will change color to indicate the reading. A green screen indicates normal blood pressure, a yellow screen indicates a risk of developing high blood pressure and red indicates high blood pressure. Measurements are automatically stored in the memory.
- Turn off this device by pressing "START/STOP", remove from your wrist by detaching hook-and-loop fasteners. If this device is accidentally left on, it will turn itself off after two minutes.

NOTE: This device will remain set on the same user after you turn it off. To change to the other user, turn this device off then press and hold "MEM" to access settings. Either the User 1 or User 2 icon will appear. Press "START/STOP" to switch to the other user. Press "MEM" six times until the screen turns off. When you press "START/STOP" again, this device will start as the other user.

### 3.3 Using Memory-Recall

This device will store up to 90 measurements each for two users. When more than 90 measurements are taken, the oldest measurement will be replaced.

- To access Memory-Recall, press and release "MEM" while this device is off.
- First, it will display the average of your three most recent measurements, indicated on screen as M-- (Measurement Average).
- Press "MEM" again to see the most recent measurement. Press "MEM" repeatedly to scroll towards the oldest measurement. On screen, M1 indicates the most recent measurement, with higher M numbers indicating older measurements.

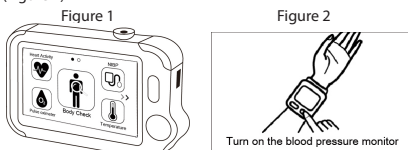
If you desire to delete all stored measurements of the current user, press and hold "MEM" until "CL" is displayed. Press "START/STOP" to confirm clearing the memory. Press and release "MEM" again and blank entry should appear on screen. Press "START/STOP" to exit.

### Use with VitalsRX, Checkme Pro and Performance Monitors

OPTIONAL: REQUIRES A SEPARATE PURCHASE

• Navigate to main menu on your VitalsRx, Checkme Pro or Performance Monitor and Tap BP menu icon in the screen upper right hand corner. (Figure 1)

• Next follow instructions on the screen to put Wrist BP Cuff on your wrist as instructed above and select Start button. Blood pressure measurements will show on our Monitor AND Wrist BP Cuff (Figure 2)



NOTE: Please also see instructions included with your Monitor purchased separately.

### 4. Cleaning and Maintenance

- For regular maintenance, this device only needs to be wiped gently with a soft, dry cloth. Never immerse this device or any components in water.
- Do not carry out repairs of any kind yourself. If a defect occurs, please contact your local authorized distributor. Use only authorized parts and accessories.

### 5. Troubleshooting

If you see any of these symbols displayed on screen, perform the corresponding correction:

**Err** Error during inflation  
**Correction:** Adjust cuff, ensuring it is wrapped properly, and repeat measurement. Do not move or talk during measurement. Ensure wrist is level with heart.

**Lo** Low battery  
**Correction:** Replace batteries following instructions in the Battery installation section

If you have the following issues without an error code, perform the corresponding correction:

**No Power** Low batteries or incorrect battery placement  
**Correction:** Ensure batteries were installed according to the + and - shown on this device. If they were, batteries need replacement.

**Measurement TooHigh/Too Low** Possible incorrect use of this device  
**Correction:** Adjust cuff, ensuring it is wrapped properly, and repeat measurement.

### 6. EMC Declaration

Guidance and Manufacturer's Declaration - Electromagnetic Immunity this device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should ensure that it is used in such an environment.

Immunity Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This device is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields from common appliances are not expected to affect the device.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7GHz	10V/m 80MHz to 2.7GHz	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	9V/m, 27V/m, 28V/m 385-5785 MHz	9V/m, 27V/m, 28V/m 385-5785 MHz	

### 7. FCC Compliance

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

- this device may not cause harmful interference, and
- this device must accept any interference received, including interference that may cause undesired operation.

Caution: Changes or modifications to this device not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance to the Instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

### 8. Specifications

1	Model	BP310B
2	Measurement Method	Oscillometric
3	Display	LCD
4	Measurement Range	Pressure: 0 to 299 mmHg Pulse: 40 to 180 beats/minute
5	Accuracy	Pressure: Within ± 3 mmHg Pulse Rate: Within ± 5% of reading
6	Inflation	Automatic inflation by pump
7	Deflation	Automatic rapid deflation
8	Pressure Detection	Semiconductor pressure sensor
9	Memory	2 persons X 90 measurements each
10	Power Supply	2 AAA alkaline batteries (not included)
11	Battery Life	About 6 months when used once a day
12	Operating Environment	Temperature 50°F (10°C) to 104°F (40°C)
		Humidity 15% to 90% (noncondensing)
		Barometric Pressure 105 kPa to 80 kPa (790 mmHg to 600 mmHg)
13	Transport Storage Environment	Temperature -4°F (-20°C) to 131°F (55°C)
		Humidity 0% to 95% (noncondensing)
14	Weight of Main Unit	Approximately 93 g (not including batteries)
15	External Dimensions	65 mm (H) X 61 mm (W) X 24 mm (D) (not including the wrist cuff)
16	Measurable Circumference of Wrist	Approximately 5.3" ~ 8.5" (13.5cm ~ 21.5 cm)
17	Electric Shock Protection	Internal power supply appliance type BF
18	Contents	Main unit, instruction manual, storage case (option)

To improve performance, these specifications are subject to change without notice.

Disposal of the device, accessories and packaging shall be carried out in accordance with national and local regulations for proper handling of waste.

### 9. Calibration and Service

The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life. It is generally recommended to have this device inspected and calibrated every two years to ensure correct functioning and accuracy. Please consult your authorized distributor.

### 10. Warranty Information

- This device is warranted to be free of manufacturing defects in workmanship and materials for a period of one year from the date listed on the purchase record, when used in accordance with the instructions provided with this device.
  - This warranty does not cover damage incurred by use of this device not in accordance with the instructions, accidental damage, or being tampered with or serviced by unauthorized service agents.
  - For repair of manufacturing defect under this warranty, please contact your local distributor within the period of the warranty. This warranty covers parts and labor only under normal operations. A transportation fee or freight fee that may be incurred will be the owner's responsibility. Any defect resulting from natural causes, e.g., flood, hurricane etc., is not within this guarantee.
  - Please note warranty does not cover damage caused by, including but not limited to: misuse or abuse; accident; the attachment of any unauthorized accessory; alteration to the product; improper installation; unauthorized repair or modification; improper use of electrical/power supply; dropped product; failure to follow required maintenance and safe-keeping; transportation damage.
- This warranty specifically excludes expendables and consumables, for example batteries. All warranty claims must be directed to the distributor responsible for the sale of the device. The content of this warranty is subject to change without further notice.

This device complies with IEC 60601-1:2005+A1:2012, IEC60601-1-2: 2014, IEC 60601-1-11:2015, IEC80601-2-30:2009+A1:2013, EN 1060-3: 1995+A2:2009

Note: To ensure accuracy, calibration by qualified technician is recommended every two years or after a repair. Please contact your authorized distributor for details

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