

TBP-6/0923 Blood Pressure Monitor



Instruction Manual

Please read all instructions carefully and retain for future use

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Know your Device

Indications for Use

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

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

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.



Warning *(continued)*

- 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 the instruction manual.

Battery Warning

- Do not mix alkaline, stand (carbon-zinc) and rechargeable batteries (nickel hydride).
- Do not mix old and new batteries.
- Non-rechargeable batteries are not to be recharged.
- Rechargeable batteries are to be removed from the unit being charged (if removable).
- Rechargeable batteries are only to be charged under adult supervision (if removable).
- Exhausted batteries are to be removed.
- The supply terminals are not to be short-circuited.
- Only batteries of the same or equivalent type as recommended are to be used.
- Batteries are to be inserted with the correct polarity (see diagram).

About Blood Pressure

BLOOD PRESSURE INDICATOR CHART

(Based on 2017 ACC/AHA guidelines)

Systolic mmHg (Upper Number)	140 & above	Stage 2 Hypertension *			→ Red
	130-139	Stage 1 Hypertension *			→ Red
	120-129	Elevated BP *			→ Yellow
	Below 120	Normal BP			→ Green
		Below 80	80-89	90 & above	
Diastolic mmHg (Bottom Number)					

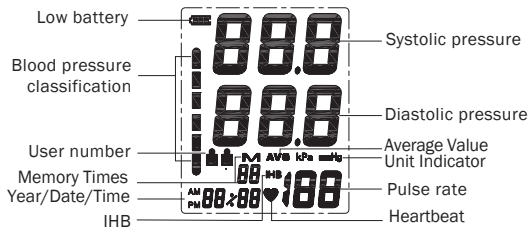
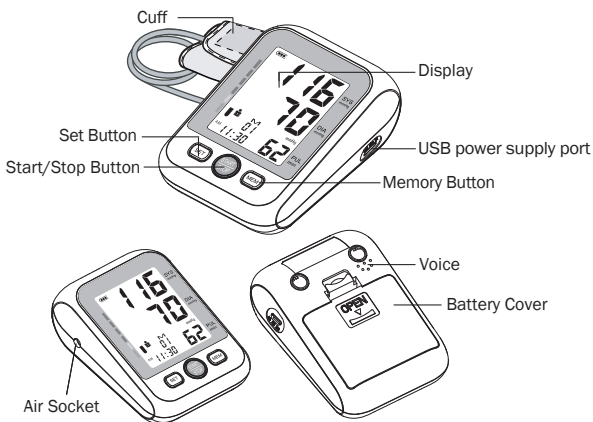
*Consult A Physician

When systolic and diastolic pressure fall into different categories, the higher pressure determines 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 for manual, electronic, or automated sphygmomanometers by the American National Standards Institute and the Association for the Advancement of Medical Instrumentation.

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.

Preparation



Set Up Your Device

Battery Installation

1. Take off the battery cover on the back of this device. (Figure 1)
2. Insert 3 AA alkaline batteries according to the + and – markings. (Figure 2)
3. Snap the battery cover on, ensure it clicks into place.

NOTE: When the low battery symbol appears on screen, turn off this device and follow the instructions above to replace batteries.

Figure 1

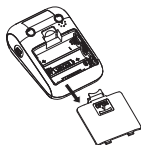
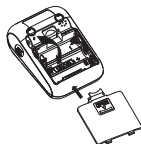


Figure 2



CAUTION

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

Setting of User

With device turned off, press and release "SET" button to show the current user.

Press "SET" button to toggle between User 1 and User 2.

To select user, press "START/STOP" to confirm and then the device turns off.

Setting of Year, Date, Time

(12-hour/24-hour System)

1. With device turned off, press and hold "SET" button until flashing year digits occur.
2. Press "MEM" to increase one year, or press and hold "MEM" to increase years. Press "SET" to confirm and then flashing month digits occur.
3. Press "MEM" to increase one month, or press and hold "MEM" to increase months. Press "SET" to confirm and then flashing day digits occur.
4. Press "MEM" to increase one day or press and hold "MEM" to increase days. Press "SET" to confirm and then flashing hour digits occur.
5. Press "MEM" to increase one hour or press and hold "MEM" to increase hours. Press "SET" to confirm and then flashing minute digits occur.
6. Press "MEM" to increase one minute or press and hold "MEM" to increase minutes. Press "SET" to confirm and then either "12" digits occur for 12-hour system or "24" digits occur for 24-hour system.
7. Press "MEM" to toggle between "12" for 12-hour system and "24" for 24-hour system. Press "SET" to confirm and then pressure unit digits occur.
8. Press "MEM" to toggle between "mmHg" and "kPa". Press "SET" to confirm and then either voice "ON" digits or "OFF" digit occur.
9. Press "MEM" to toggle between voice "ON" and "OFF". Press "SET" to confirm and flashing year occur again, or press "START/STOP" to confirm and then the device turns off.
10. Setting is completed.

Note: Pressing "START/STOP" will confirm the setting and then the device turns off at any time.

Before Taking a Measurement

- For most accurate results, measurements should be taken in the same circumstances and at the same time every day.
- This device can be applied to either arm, but preferably the left. Use the same arm for each measurement.
- Any blood pressure recording can 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.

Measurement

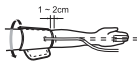
1. This device should be used on bare skin. If necessary, loosely roll up your sleeve to expose arm.

Note: your arm cannot be tightened by your sleeve.

2. With the hose down the inside of your arm and the bottom of the cuff approx. 1-2cm above your elbow, wrap the cuff around your arm. Secure the cuff with a finger space between the cuff and your arm by attaching hook-and-loop fastener.

3. Comfortably seated

- Legs uncrossed
- Feet flat on the floor
- Back and arm supported
- Relax as much as possible and do not talk during the measurement.



Measurement *(continued)*

4. 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".
6. When a pulse is detected, a heart symbol will flash on screen.
7. When measurement is complete, the cuff deflates automatically and your systolic, diastolic, and pulse rate will display on screen.
8. Turn off this device by pressing "START/STOP", remove from your arm 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 release "SET" to access user setting. Either the User 1 or User 2 icon will appear. Press "SET" to switch to the other user icon and press "START/STOP" to confirm the user and then the device turns off.

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.

1. To access Memory-Recall, press and release "MEM" while this device is off.
2. First, it will display the average of your three most recent measurements, indicated on screen as M AVG (Measurement Average).
3. Press "MEM" again to see the most recent measurement. Press "MEM" repeatedly to scroll towards the oldest measurement. On screen, M01 indicates the most recent measurement, with higher M numbers indicating older measurements.
4. If you desire to delete all stored measurements, press and hold "SET" under the Memory-recall status until "dEL no" is displayed with "no" flashing. Press and release "SET" to switch to "dEL YES" with "YES" flashing.
5. Press "START/STOP" with "dEL YES" to confirm clearing the memory and then blank entry appears on screen, or press "START/STOP" with "dEL no" to go back to the Memory-recall status without clearing the memory.
6. Press "START/STOP" to exit.

Care 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.

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 cuff 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 Too High / Too Low

Possible incorrect use of this device

Correction: Adjust cuff, ensuring it is wrapped properly, and repeat measurement.

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	

EMC Declaration

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 9V/m, 27V/m, 28V/m 385-5785 MHz	10V/m 80MHz to 2.7GHz 9V/m, 27V/m, 28V/m 385-5785 MHz	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.

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


- (1) this device may not cause harmful interference, and
- (2) 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.

Specifications

1	Model	TBP-6/0923	
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 $\pm 5\%$ 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	3 AA 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 115 g (not including batteries)	
15	External Dimensions	103 mm (H) X 77.5 mm (W) X 40.8 mm (D)	
16	Measurable Circumference of arm	22 ~ 36cm	
17	Electric Shock Protection	Internal power supply appliance type BF	
18	Contents	Main unit, Cuff, instruction manual	

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.

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 2 years to ensure correct functioning and accuracy. Please consult you authorized distributor.

Warranty Information

WARRANTY DURATION: All materials and workmanship are warranted to the original consumer purchaser for a period of ninety (90) days from the original purchase date.

WARRANTY COVERAGE: This product is warranted against defective materials or workmanship. This warranty is void if the product has been damaged by accident, in shipment, unreasonable use, misuse, neglect, improper service, commercial use, repairs by unauthorized personnel or other causes not arising out of defects in materials or workmanship. This warranty does not cover the following which may be supplied with product, including but not limited to; LCD Screens, glass parts, lenses, bulbs etc. This warranty is effective only if the product is purchased and operated in USA, and does not extend to any units which have been used in violation of written instructions furnished by manufacturer or to units which have been altered or modified or, to damaged products or parts thereof which have had the serial number removed, altered, defaced or rendered illegible.

WARRANTY PERFORMANCE: During the above 90 day warranty period, a product with a defect will be either repaired or replaced with a reconditioned comparable model (at manufacturer's option). The repaired or replacement product will be in warranty for the balance of the 90 day warranty period and an additional one-month period. No charge will be applicable for such repair or replacement. **SERVICE AND REPAIR:** If service is required for this product, you should first contact Nuvomed Inc. Customer Service at info@nuvomed.us or by calling Toll-Free Number 1 (877) 612-5619, Monday to Friday 10 am to 6pm EST.

NOTE: Manufacturer cannot assume responsibility for loss or damage during incoming shipment. As a precautionary measure, carefully package the product for shipment, and insure it with the carrier. Be sure to enclose the following details with the product: your full name, return address and daytime phone number, a note describing the problem you experienced, a copy of your sales receipt or other proof of purchase to determine warranty status. C.O.D. shipments cannot be accepted.

This manufacturer's product warranty extends to the original consumer purchaser of the product. Neither the retailer nor any other company involved in the sale or promotion of this product is a co-warrantor of this manufacturer warranty.

WARRANTY DISCLAIMERS: This warranty is in lieu of all warranties expressed or implied and no representative or person is authorized to assume for manufacturer any other liability in connection with the sale of our products. There shall be no claims for defects or failure under any theory of tort, contractor commercial law including but not limited to, negligence, gross negligence, strict liability, breach of warranty and breach of contract. Under no circumstances will Manufacturer's / Distributor's maximum liability exceed the retail value of the product.