PRIVA® COMPACT

Upper Arm Electronic Blood Pressure Monitor

Model: BP101A



Thank you for choosing the Priva® Compact Upper Arm Electronic Blood Pressure Monitor. Please read this user manual carefully before using the device to ensure its safe and proper operation. Retain this manual for future reference should you require assistance or encounter any issues.

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1. Introduction

This digital blood pressure monitor uses the oscillation method to measure blood pressure (BP). This means that the monitor can detect the movement of your blood in the brachial artery and convert your blood pressure into a digital reading. This monitor automatically detects blood pressure without a stethoscope and is easy to use.
Each measurement result will be displayed on the screen and automatically stored. Memory Capacity: 2 users x 500 measurements.
This unit features a blood pressure classification index, making it easy to check your blood pressure.

1.1 Measurement Principle:

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" equivalent to the atmospheric pressure. The unit inflates the arm cuff and detects pressure oscillations generated by beat-to-beat pulsation, which are used to determine systolic pressure, diastolic pressure, and pulse rate.

2. Symbol Description

2.1 Warning / Precaution Symbols

The warning signs and symbols throughout this manual ensure safe and correct use of the device, protecting you and others from harm. Warning marks and graphic symbols are described as follows:

⚠ Warning	A warning alerts the reader about a situation which, if not avoided, could result in death or serious injury and may also describe potential serious adverse reactions and safety hazards.

⚠ Precautions	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury, property damage, or device malfunction. It also alerts against unsafe practices to ensure safe and effective use.
Contra-indications	Contraindications are conditions under which the device should not be used because the risks clearly outweigh any possible benefits. Certain individuals should not use the device due to their health status.
Notes	Indicates the need for attention; neglect may lead to incorrect use of the product or damage to the device.

2.2 Other Symbols

(symbol)	Applied Part: Type BF	(symbol)	Type of Protection Against Electric Shock: Class II
(symbol)	Refer to Instruction Manual	(symbol)	Manufacturer
(symbol)	Disposal in Accordance with Directive 2012/19/EU (WEEE)	MD	Medical Device
SN	Serial Number	(symbol)	Date of Manufacture
MR	This device has not been tested for use in an MR environment and should not be exposed to MR environments while patients are wearing the device. Keep it outside the MRI scanner room.		
IP21	First Number (2): Protected against solid foreign objects with a diameter of 12.5mm and greater Second Number (1): Protected against vertically falling water drops.		
CE 2460	CE Mark: conforms to essential requirements of EU MDR 2017/745		

3. Intended Use

The Upper Arm Electronic Blood Pressure Monitor is intended to measure systolic and diastolic blood pressure, as well as pulse rate, in individuals aged 12 years and older. This device is designed for use in home and clinical/hospital environments.

4. Safety Information

4.1 Contraindications

⚠ **Warning**

- The device is not suitable for use on women who are or may be pregnant.
- The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, or defibrillators.
- DO NOT adjust medication based on readings from this Upper Arm Electronic Blood Pressure Monitor. Take medication as prescribed by your doctor. Only a healthcare professional is qualified to diagnose and treat High Blood Pressure.
- Consult your doctor before using the device if you have any of the following conditions: common arrhythmias such as atrial or ventricular premature beats, atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pregnancy, pre-eclampsia, or renal diseases.
- NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- Do not use the device on the injured arm or the arm under medical treatment.
- Do not apply the cuff on the arm while on an intravenous drip or blood transfusion.
- Do not use the device with other medical electrical (ME) equipment simultaneously.
- Do not use the device in the area of high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanner. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.

- DO NOT use this monitor in oxygen-rich environments or near flammable gases.
- Please ask your doctor about your normal blood pressure for guidance before taking measurements yourself.
- This product is suitable only for individuals aged 12 years and older. Please keep the unit out of reach of infants, toddlers, and young children.
- Do not service or maintain the device while in use.
- Do not plug or unplug the AC/Type-C adapter with wet hands.
- Only use the original cuff, power adapter, and batteries specified in this user manual. Unauthorised accessories can damage the device or lead to inaccurate readings.

⚠ **Precautions**

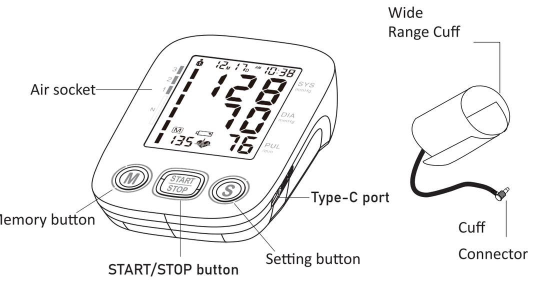
- If the cuff causes discomfort, press the START/STOP button immediately to switch the device off and consult your doctor.
- Do not kink the connection tubing. Continuous cuff pressure may restrict blood flow, potentially causing injury.
- Do not take measurements more often than necessary; restricted blood flow may cause bruising.
- Do not apply the cuff over a wound or skin injury, as this may worsen the condition.
- Consult with your doctor before using this monitor on a arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury.
- Consult with your doctor before using this monitor if you have had a mastectomy or lymph node clearance.
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading. Cuff inflation may temporarily interrupt the function of other medical electrical (ME) equipment monitoring the same limb.
- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.
- Consult your doctor before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- DO NOT use this monitor for any purpose other than measuring blood pressure.
- DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This may damage the monitor.
- Do not use or store the monitor and cuff in direct sunlight, extreme temperatures, high humidity (see Specifications), or near fire or water. Doing so may result in inaccurate readings or damage to the device.

- DO NOT use this monitor in a moving vehicle such as in a car.
- This device is calibrated during manufacturing and does not require periodic recalibration when used properly. If you frequently experience inaccurate readings, please contact your local distributor.
- Do not disassemble, repair, or remodel the main unit or the cuff of the Upper Arm Electronic Blood Pressure Monitor by yourself. If necessary, contact your local distributor.
- Do not drop the monitor or subject device to strong shocks or vibrations.
- ONLY use this monitor on persons whose arm circumference is within the specified range of the cuff.
- Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.
- Store the unit high up and out of reach of children. Small components, including batteries, battery covers, and plastic bags, pose a risk of asphyxiation or choking.

Note:
The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5 and ISO 10993-10/23. It will not cause any potential sensitization or irritation reaction.

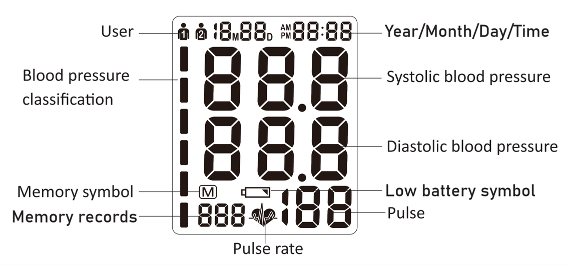
5. Product Description

5.1 Main Unit



Component	Description Function
Setting button (S)	Press the S button when powered off to enter the setting mode. In setting mode, press this button to confirm the setting value; Assists in clearing memory.
START/STOP button	Switch the device ON/OFF. Assists in clearing memory.
Memory button (M)	In setting mode, press this button to enter the memory mode.
LCD display	Displaying information of measurement, battery power etc.
Type-C port	Connect to the USB power cable.
Air socket	Connect to the air hose (cuff).

5.2 LCD Display



Item	Description
User	Monitor is operated by User 1. Monitor is operated by User 2.
Blood pressure classification	Identifies your blood pressure category (refer to section 6.4.6)
Memory symbol & Memory records	Indicates that the device is in memory mode and displays the selected memory group.

Low battery symbol	Indicates that the battery power is low.
Pulse rate	Measurement data of pulse rate.
Systolic blood pressure (SYS)	Systolic blood pressure reading in mmHg (refer to section 7.1 for more information)
Diastolic blood pressure (DIA)	Diastolic blood pressure reading in mmHg (refer to section 7.1 for more information)
Year/Month/ Day/ Time	Date and Time format: Year/Month/Day/ Time

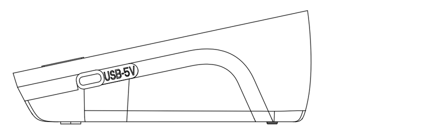
5.3 Component List

Parts	Quantity	Description
Upper Arm Electronic Blood Pressure Monitor	1	BP101A
Batteries	4	AAA
Cuff (with air hose)	1	22cm~32cm
User Manual	1	-

6. Operating Instructions

6.1 Power Supply

This product has two power supply modes:
a) Battery power mode: Use 4x AAA 1.5V batteries.
- For details about battery installation and replacement, see section 6.2 of this user manual.
b) AC/Type-C power mode: Use a 5V 1.0A AC/Type-C adapter.
- If you choose to use the AC/Type-C adapter powered mode, please note: Before measurement, insert the Type-C output end of adapter into the AC/Type-C port of main unit; then plug the AC/Type-C adapter into the AC socket.



Unplug the adapter from the AC socket when you finish the measurement.

Important to note:
When the main unit is connected to the AC/Type-C adapter, it will be AC/Type-C adapter powered, regardless of whether the main unit is equipped with batteries; when the AC/Type-C adapter is disconnected from main unit, it will automatically switch to battery power mode.

A power adapter is not supplied with this product. Please purchase a compatible power adapter separately before use. The purchased adapter must meet the following specifications:
Input voltage: 100~240V, Output: 5V±5% 1.0A

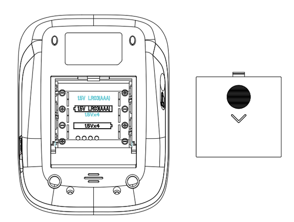
⚠ **Caution:**

Using an incorrect or low-quality power adapter may compromise device safety, resulting in property damage or personal injury. If purchasing an adapter separately, ensure it is a medical-grade Type-C 5V 1.0A adapter certified to IEC 60601-1 or IEC 62368-1, with 2MOPP isolation between primary and secondary circuits.

6.2 Installing and Replacing the Batteries

For initial setup using battery power, ensure the batteries are installed prior to switching the device on. If the low battery symbol is displayed on the LCD, it means the battery is low and the device is unable to provide accurate measurements. Please replace the batteries.

a) Remove the battery cover from the battery compartment, following the arrow direction indicated on the battery cover.
b) Install or replace 4x AAA batteries as indicated in the battery compartment observing the indicated polarity.



c) Close the battery cover.

Important:

- To replace batteries, switch your monitor off and remove all batteries. Then replace with 4 new alkaline batteries at the same time.
- ONLY use 4 "AAA" alkaline batteries with this monitor. DO NOT use other types of batteries. Do not use new and used batteries together. DO NOT use different brands of batteries together.
- DO NOT insert batteries with their polarities incorrectly aligned.
- Remove batteries if this monitor will not be used for an extended period (more than 3 months) of time.
- DO NOT use batteries after their expiration date.
- Periodically check batteries to ensure they are in good working condition. If the batteries are bulging or leaking, replace the batteries before use.
- Dispose of batteries according to your local regulations.

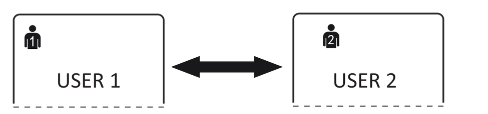
Note:

- The four batteries supplied with the product can ensure the power consumption for at least 300 measurements.

6.3 System Settings

a) User Settings

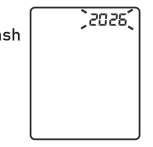
Press the S button when powered off to enter the Settings mode. The screen will display 1/2. Press the M button to switch between 1 and 2, press the S button to confirm the user.



b) Setting the Date and Time

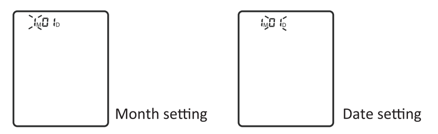
It is important to set the Date and Time before using your Upper Arm Electronic Blood Pressure Monitor, to ensure a time stamp can be assigned to each measurement that is stored in the memory.

Setting the Year, Month and Day:
Following the previous step, the Year display will flash on the screen.
Press the M button to adjust the year by one digit at a time (range: 2026 to 2099).
Press the S button to confirm.



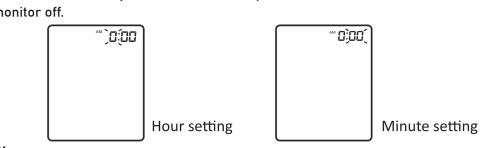
Year setting

Next, the month digits will flash on the screen.
Press the M button to adjust the month (1 to 12).
Press the S button to confirm the month. The day digits will then start flashing.
Press the M button to increase the digits (choose from 1 to 31). Press S button to confirm the date. The device will then enter the hour and minute setting mode.



Month setting   Date setting

Setting the Hour and Minute:
Once the Date is set, you will enter the time setting mode. The hour digits will flash on the screen. Press the M button to adjust the hour (1 to 12 AM / 1 to 12 PM).
Press the S button to confirm the hour. The minute digits will then start flashing.
Press the M button to adjust the minutes (00 to 59), then press S to save.
The LCD will display "CL" when the settings are completed. Press the S button to confirm.
The monitor is now ready to use. You can also press the "START/STOP" button to switch the monitor off.



Hour setting   Minute setting

Note:
If the batteries are removed for 30 seconds or longer, the date and time will return to the default value.

6.4 Proper Use of the Unit

6.4.1 Pre-measurement

a) Check the device before use:
- Check the monitor to ensure that the main unit and cuff are free from damage and cracks.
- Check the batteries to ensure there is no chemical leakage. If there is leakage, please replace the batteries before use.
- Check whether the display is normal and without E-X(X stands for Arabic numerals) prompt. When an E-X appears, follow section 9.
- If the low battery icon is present, please replace the batteries before use.

b) Several factors may influence the blood pressure measurement result. Avoid eating, drinking alcohol or caffeine, smoking, exercise and bathing for at least 30 minutes before taking a measurement.
c) Please sit quietly for at least 5 minutes before taking the blood pressure measurement.
d) A single measurement does not provide an accurate indication of your true blood pressure. We recommend taking at least two measurements to ensure an accurate reading. Wait at least 1 minute between measurements, to allow your blood circulation to recover.
e) Stress raises blood pressure. Avoid taking measurements during stressful times.
f) Try to measure your blood pressure regularly at the same time every day, as blood pressure fluctuates throughout the day.
g) For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a healthcare professional.
h) Factors affecting blood pressure measurement
- Tensing or straining your arm during a measurement may increase your blood pressure reading.
- If the cuff around the arm is lower than the height of the heart, the blood pressure may be higher.
- Too loose or too tight cuffs may result in inaccurate readings.
- In different postures, environments and physical conditions, the measured blood pressure values may be different.

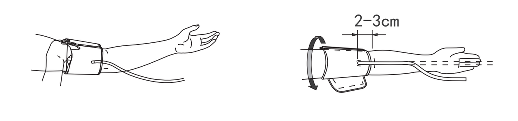
6.4.2 Fitting the Cuff

a) Firmly insert the air hose connector into the air socket of the main unit.

b) Remove all jewellery, such as watches and bracelets from your left arm.

Roll or push up your sleeve to expose the skin, or wear thin clothing. Ensure your sleeve is not too tight.

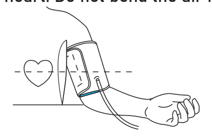
c) Hold your arm with your palm facing upward, and, wrap the cuff over the upper arm. Position the tube off-center towards the inside of the arm in line with the ring finger. Ensure that the lower edge of the cuff is approximately 2 to 3 cm above the elbow and the air hose is positioned on the inside of the arm.



d) Secure the cuff with the velcro that it fits firmly, but it not too tight. For optimal fit, you should be able to insert two fingers comfortably beneath it.

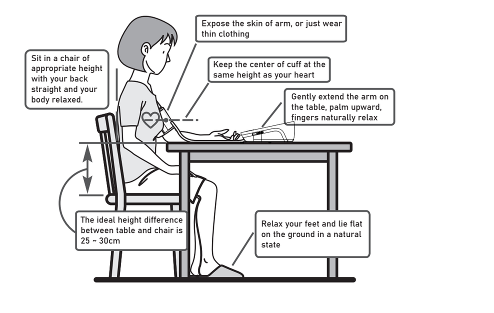


e) Place your arm on a table (palm facing upwards) so that the cuff is at the same height as your heart. Do not bend the air hose.



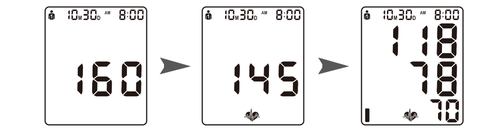
6.4.3 Sitting Correctly

a) Sit comfortably upright in a chair with your feet flat on the floor.
b) Place your elbow on a table so the cuff is at the same level as your heart. Rest your arm on the flat surface, palm facing upwards. Keep your arm and hand relaxed. Do not clench your fist or bend your arm.
c) Take 5~6 deep breaths before starting measurement.



6.4.4 Start the Measurement

Once the cuff is correctly positioned on your arm, start the measurement as follows:
Press the "START/STOP" button. All symbols will appear on the display for 2 seconds.
Remain still and do not move or talk until the entire measurement process is completed. The monitor will automatically measure your blood pressure according to the following procedure:
Step 1: The monitor will inflate the cuff. The rising pressure in the cuff will be displayed.
Step 2: Once the target pressure is reached, the pump will stop, and the pressure will gradually diminish. If the inflation is insufficient to take a reading, the device will automatically inflate to a higher pressure. When the device detects the signal, the heart symbol on the display starts to flash.
Step 3: When the measurement has been completed, the systolic, diastolic and pulse rate will be displayed on the screen.

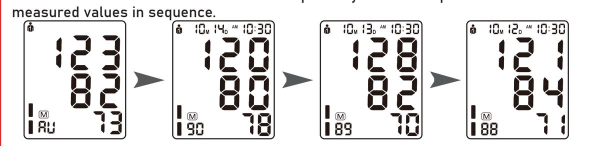


Discontinuing a Measurement:
If it is necessary to interrupt a blood pressure measurement for any reason (e.g., the patient feels unwell), the "START/STOP" button can be pressed at any time. The device will immediately decrease the pressure in the cuff.

6.4.5 Memory-recall of Measurements

The blood pressure monitor automatically stores 2x 500 sets of measurement values. The oldest record will be replaced by the latest measurement value when there are more than 500 readings for each user.

a) Recalling a Memory Record
With the device switched off, press the M button. The monitor will display the stored readings for the currently selected user profile. The average of the last 3 measurements will be displayed. Press the M button again to display the last measurement taken. Press the M button repeatedly to view the previous measured values in sequence.



- If there are only two readings in memory the average of the last 2 readings will be displayed; if there is one reading in memory, the last measurement will be displayed;
- If no measurement before, the LCD will display user ID, the memory icon and "no".

b) Clearing the Memory
Delete all stored records:
With the device switched off, press the S button. 1/2 will be displayed. Press the M button to select the user to delete the memory, and press the S button until "CL" appears.
Press the "START/STOP" button. "CL" will flash to clear all memories of the current user.
- When the memory reaches maximum capacity, new data will overwrite the oldest data.
- Removing the batteries will not result in loss of stored readings.

6.4.6 Blood Pressure Classification Function:

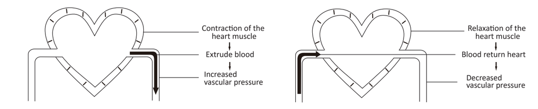
This monitor features a blood pressure classification indicator that identifies your blood pressure category via the display bar :

Display of Prompt bar	Blood pressure category	Systolic blood pressure (SYS)	Diastolic blood pressure (DIA)
▬	NORMAL	< 120 mmHg	< 80 mmHg
▬	NORMAL	120-129 mmHg	80-84 mmHg
▬	HYPERTENSION STAGE 1	130-139 mmHg	85-89 mmHg
▬	HYPERTENSION STAGE 2	140-159 mmHg	90-99 mmHg
▬	CONSULT YOUR DOCTOR IMMEDIATELY	160-179 mmHg	100-109 mmHg
▬	CONSULT YOUR DOCTOR IMMEDIATELY	⩾ 180 mmHg	⩾ 110 mmHg

7. About Blood Pressure

7.1 Systolic- and Diastolic Blood Pressure

Blood pressure is the pressure exerted on the arteries. The systolic blood pressure value represents the blood pressure produced by contraction of the heart muscle. The diastolic blood pressure value represents the blood pressure produced by relaxation of the heart muscle.



7.2 Standard Blood Pressure Classification

According to 2017 Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure, blood pressure can be classified as:

BP Category	SYS	DIA
Normal	<120 mm Hg	<80 mm Hg
Elevated	120-129 mm Hg	<80 mm Hg
Hypertension		
Stage 1	130-139 mm Hg	80-89 mm Hg
Stage 2	⩾140 mm Hg	⩾90 mm Hg

BP indicates blood pressure (based on an average of ⩾2 careful readings obtained on ⩾2 occasions).

Systolic Blood Pressure (SYS) of > 180 mmHg and/or Diastolic Blood Pressure (DIA) of > 120mmHg should be treated as a Hypertensive Crisis.

Source: Whelton et al. Hypertension 2018; 71(6): 1269–1324.

⚠ **Warning**

- Only a doctor or healthcare professional can determine your normal blood pressure range and assess whether a reading is dangerously high or low. Please contact your doctor if your measurements fall outside your normal range.

8. Care And Maintenance

8.1 Cleaning and Disinfection

This device is suitable for multi-patient use and must be cleaned and disinfected between uses as necessary. Thoroughly clean the main unit, air hose, and cuff. Ensure the cuff is fully disinfected. Wait 10 minutes after cleaning/disinfection before use.
Wash your hands or use hand sanitiser before cleaning the device.
Clean/disinfect the accessories at room temperature 5-40℃.

8.1.1 Cleaning method:
a) Clean the device with a soft cloth dampened with soapy water until no visible contaminants remain.
b) Wipe the cleaning solution off of the device with a soft cloth dampened with tap water until no visible cleaning agent remains.
c) Air dry the device thoroughly after cleaning.

8.1.2 Disinfection method:
Clean the cuff first following the steps above.
a) Disinfect the cuff with a soft cloth dampened with 70% isopropanol for 3 minutes.
b) Leave the cuff at room temperature for 10 minutes to allow any remaining disinfectant to evaporate completely.

Note:
- Do not use gasoline, diluent or other harsh chemicals to clean the device, as this may result in malfunction, discolouration, or damage to internal and external components.
- Do not hold the device under running water, or submerge it in water or other liquids.
- Ensure that no liquid penetrates into the device. If this happens, only use it again after the device is completely dry.
- Ensure that the device is switched off and the AC/Type-C adapter is disconnected from the AC port when cleaning/disinfecting the device.

8.2 Calibration

The Upper Arm Electronic Blood Pressure Monitor is calibrated during manufacturing. If this monitor is used according to the use instruction, periodic re-calibration is not required. If any time your doubt the accuracy of measurement, please contact your local distributor. The service life of the monitor is 5 years. Once the service life of monitor exceeds 5 years, replace the monitor with a new Upper Arm Electronic Blood Pressure Monitor.

8.3 Storage

Store your monitor in its original packaging when not in use, as per the storage requirements in the Specifications section of this user manual.
Do not store your monitor :
- If your monitor is wet.
- In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
- In locations exposed to vibrations or shocks.

9. Error Codes and Troubleshooting

Error Indicators
The following symbols will appear on the display when there is an error.

Symbol	Cause	Correction
E-1	Weak signal or sudden pressure change	1) Wrap the cuff properly around the arm, using the correct size cuff. 2) Remeasure.
E-2	Strong external disturbance	1) Ensure there are no external radiating devices. 2) Remain still and keep quit while remeasuring.
E-3	Error during inflation	1) Wrap the cuff properly around the arm, using the correct size cuff. 2) Ensure that the air hose is properly inserted into the air socket. 3) Remeasure.
E-5	Abnormal blood pressure	Repeat measurement after relaxing for 30 minutes. If three consecutive unusual readings are recorded, contact your doctor.
(low battery symbol)	Low battery	Replace with 4 new AAA batteries.

Troubleshooting:

Problem	Check	Solution
No power	Check: Is the monitor battery powered? Solution: Replace with 4 new AAA batteries.	Check: Is the monitor battery powered? Solution: Replace with 4 new AAA batteries.
	Check: Is the monitor AC/Type-C adapter powered? Solution: Ensure the Type-C adapter is securely inserted into the monitor and AC socket.	Check: Is the monitor AC/Type-C adapter powered? Solution: Ensure the Type-C adapter is securely inserted into the monitor and AC socket.
No inflation	Is air hose connector securely inserted into the air socket?	Reinsert securely.
		Replace with new cuff
Cuff leak	Is the cuff loose?	Wrap the cuff tightly.
	Is the cuff broken?	Replace with new cuff.

Note: Please contact the distributor if you can't solve the problem. Do not disassemble the unit by yourself!.

10. Specifications

Measurement method	Oscillometric method
Measurement site	Upper Arm
Pressure display range :	0-299 mmHg
Measurement range :	Pressure measurement range: SYS: 50-255 mmHg DIA: 30-200 mmHg Pulse measurement range: 40-199 beats/minute
Accuracy :	Pressure: ±3mmHg Pulse value: ±5% of reading
Measuring resolution :	1 mmHg
Memories recall	2x 500 sets memory of measurement values
Display	LCD digital display
Dimensions of main unit	L130mm x W97mm x H50mm
Weight of main unit	228g (batteries not included)
Power supply	4pcs AAA alkaline batteries / Type-C 5V 1.0A
Measurable arm circumference	22 cm to 32 cm
Operating conditions	Temperature range of 5-40℃, Relative humidity range of 15-93% RH, Atmospheric pressure range of 86-106 kPa
Storage & transportation conditions	Temperature range of: of -20℃ to 55℃, Relative humidity range of 10-93% RH, Atmospheric pressure range of 86-106 kPa
Protection against electric shock	Battery Powered Mode: Internally powered ME equipment AC Adapter Powered Mode: Class II ME Equipment
Service life of 5-40℃	5 years
Shelf life	No shelf life requirement
Ingress of waterproof	IP21
Applied part	Type BF (arm cuff)
Software version	GA1.0
No Sterilize requirement	
Not category AP / APG equipment	
Mode of operation: Continuous operation	

11. Clinical Testing Summary

This monitor has been clinically investigated according to the requirements of ISO 81060-2:2018. In the clinical validation study, the cuffs were tested for clinical accuracy with the main unit. Testing was conducted on 90 participants per cuff, including individuals aged 12 years and older, as well as patients with diabetes and hypertension (pregnant women were excluded). The sample group included at least 30% male and 30% female distribution.
Summary of clinical validation: No safety problems or adverse events were found during the clinical test. The test results show that the Upper Arm Electronic Blood Pressure Monitor meets the requirement of IEC 80601-2-30:2018.

12. Disposal

Dispose of your monitor and other components according to local regulations. Improper disposal may cause environmental pollution. Dispose of used batteries in accordance with local regulations.

13. Electromagnetic Compatibility

Statement:
This equipment is intended for use in both home healthcare and professional healthcare environments, maintaining the following essential performance:

Essential Performance:
According to IEC 80601-2-30: 2018, we have conducted EMC testing based on the following essential performance:

Accuracy:	Pressure: within ±3mmHg (0.4kPa) Pulse value: ±5%

If Essential Performance is lost or degraded due to electromagnetic disturbances, this may result in inaccurate measurement and mislead patients. Please read the important information below to avoid any possible electromagnetic disturbances.

Warning:
- Using a cell phone, microwave oven, HF surgical equipment, magnetic resonance imaging or other radio radiant equipment near this product, may cause malfunction or lead to loss of essential performance, which will affect the measurement accuracy.
- Use of this equipment adjacent to or stacked with other equipment should be avoided, as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the monitor, as it will affect the performance of the equipment.
- Use of accessories and transducers other than those specified or provided by the manufacturer of this equipment, could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Caution:
- Security, antitheft, metal detectors and radiofrequency identification (RFID) devices may affect the monitor. Do not use monitor near these places. If you have to go through one of these devices, switch your monitor off. Before each use, check the status of your monitor to ensure it is operating normally.
- Using short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy and electrocautery devices near this product may cause malfunction or lead to loss of essential performance. Do not use monitor near this equipment. Before each use, observe the device to verify that it is operating normally.

Guidance and manufacturer's declaration – electromagnetic emission

The Blood pressure monitor is intended for use in the electromagnetic environment specified below. The user of the Blood pressure monitor should ensure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
Conducted and Radiated RF emissions CISPR 11	Group 1 Class B	The Blood pressure monitor uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted RF emissions CISPR 11	Group 1 Class B	The Blood pressure monitor is suitable for use in all establishments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes , except near active HF surgical equipment and RF shielded room for magnetic resonance imaging.
Radiated RF emissions CISPR 11	Group 1 Class B	

Guidance and manufacturer's declaration – electromagnetic immunity

The Blood pressure monitor is intended for use in the electromagnetic environment specified below. The user of the Blood pressure monitor should ensure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge IEC 61000-4-2	±8kV contact; ±2kV, ±4kV, ±8kV, ±15 kV air	±8kV contact; ±2kV, ±4kV, ±8kV, ±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%.
Radiated RF EM fields IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz or 2Hz	10V/m (Home healthcare environment): 80MHz – 2.7GHz 80% AM at 1kHz or 2Hz	Power quality should be that of a home healthcare environment and a professional healthcare facility environment.
Electrical fast transients/bursts IEC 61000-4-4	±2kV AC power supply lines; ±1kV DC power/Signal lines. 100 kHz repetition frequency	±2kV AC power supply lines;	Power quality should be that of a home healthcare environment and professional healthcare facility environment.
Surges IEC 61000-4-5	±0.5kV, ±1kV lines to lines; ±0.5kV, ±1kV, ±2kV lines to earth	±0.5kV, ±1kV lines to lines;	Power quality should be that of a home healthcare environment and professional healthcare facility environment.
Conducted disturbances induced by RF fields:IEC 61000-4-6	3V 0.15MHz – 80MHz, 6V in ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz	3V 0.15MHz – 80MHz, 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	Power quality should be that of a home healthcare environment and professional healthcare facility environment.
Note: The ISM (industrial, scientific, and medical) bands between 0.15 MHz and 80 MHz are 6765 kHz to 6795 kHz; 13553 kHz to 13567 kHz; 26957 kHz to 27283 kHz; and 4066 kHz to 4070 kHz.			
The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7.0 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz, and 50.0 MHz to 54.0 MHz.			
Rated power frequency magnetic fields IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz	Power frequency magnetic fields should be at levels characteristic of a home healthcare environment and professional healthcare facility environment.
Voltage dips IEC 61000-4-11	0% UT, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° ;0% UT, 1 cycle and 70% UT, 25 /30 cycle Single phase: at 0°	Applicable	Power quality should be that of a home healthcare environment and professional healthcare facility environment.
Voltage interruptions IEC 61000-4-11	0% UT, 250/300 cycle	Applicable	

NOTE: UT is the a.c. mains voltage prior to application of the test level.E.g.: 25/30 means 25 periods at 50 Hz or 30 periods at 60 Hz.

Guidance and manufacturer's declaration – electromagnetic immunity

The Blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood pressure monitor should ensure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See the following table	Complies	
Proximity magnetic fields IEC 61000-4-39	See the following table	Complies	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation	Immunity Test Level(V/m)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	28
1720 1845 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	28
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.
a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz, While it does not represent actual modulation, it would be worst case.

Test specifications for enclosure port immunity to proximity magnetic files

Test frequency	Modulation	Immunity test level (A/M)
30 kHz a)	CW	8
134.2 kHz	Pulse modulation b) 2.1 kHz	65 c)
13.56 MHz	Pulse modulation b) 50 kHz	7.5 c)

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the home healthcare environment.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) r.m.s, before modulation is applied

14. Travel or International Use

Since the accuracy of the Blood Pressure Monitor will be affected by the external environment, in view of the uncertainty and instability of the travel environment, please do not use the Electronic Blood Pressure Monitor during travel or on an aircraft.
The Blood Pressure Monitor can be used internationally, but it must be used and stored in the environment specified in this user manual.
Since the power supply mode of the AC/DC adapter of the monitor may be incompatible with foreign power supply systems, please do not use AC/DC power supply mode in foreign countries, but only use the device under the battery power supply mode. To ensure that the Electronic Blood Pressure Monitor is not affected during carrying, please check the following items before use to ensure it can operate normally:
- Check the monitor to ensure that the main unit and cuff are free from damage and cracks.
- Check to ensure there is no battery leakage, and replace batteries if needed.
- Check whether the display is normal and that there is no E-X prompt displayed.

If you notice any abnormalities, stop using the device immediately.

15. Warranty

- The unit is guaranteed to be free of defects in workmanship and materials under normal use for a period of Five Years from the date listed on the purchase record.
- Claims for repair under this warranty must be reported to your local distributor within the active warranty period. Coverage is strictly limited to parts and labour under standard operating conditions. Any defect resulting from natural causes (e.g., flood, hurricane, etc.) is excluded from this warranty.
- This warranty does not cover damage incurred by use of the unit contrary to the user instructions, or being tampered with or serviced by unauthorized service agents.

Monitor subjected to misuse, abuse, and neglect of this manual's content, non-instructional purposes, unauthorized repair or modifications will be excluded from this warranty.

16. Manufacturer Information:

Manufacturer:
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MADE IN CHINA

For self-testing.

MRN: GA260827
MARN: BP101A 260827

CE 2460 ⚠ IVD

REV.00

尺寸：450*390mm
红色为切线，绿色为折线，风琴折
材质:80g书写纸 单黑 折页 双面印刷