Arm Blood Pressure Monitor

User Manual

Model: ARM-90B
Manual version: A3
Issue date:2024-03

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Thank you for purchasing the Arm Blood Pressure Monitor. The monitor uses the oscillometric method of blood pressure measurement. This means the monitor detects your blood movement through your brachial artery and converts the movements into a digital reading.

The device can be used in homecare environment, and the patient is an intended operator, and all the functions can be safely used.

This monitor complies with the requirements of ISO 81060-2.

1. Unpacking Inspection

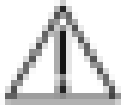
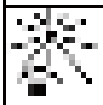
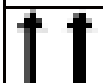
Before use, please open the package carefully and check whether all the parts are available according to the following packing list and whether the parts are damaged during transportation, and then install and operate in strict accordance with the user manual.

2. Packing List

No.	Name	Quantity
1	Arm Blood Pressure Monitor	1
2	Cuff 22~42cm (8.6~16.5 inches)	1
3	Pouch	1
4	User Manual	1
5	Quick Start Guide	1

3. Symbol Definition

Knowledge of the warning signs and symbols is crucial to the safe and proper use of this device. Kindly get informed on the following signs and symbols which you might encounter within this user manual or on the label:

	Caution
	TYPE BF APPLIED PART
	Symbol for the marking of electrical and electronics devices according to Directive 2012/19/EU.
	Refer to instruction manual
	Keep dry
	Low voltage prompt
	Keep away from the sunlight
	Vertical upward

IP21	2 Protected against solid foreign objects of 12.5 mm Ø and greafer； 1 Protection against vertically falling water drops
RoHS	RoHS mark
CE 0123	CE mark
	Manufacturer
	Date of manufacture
SN	Serial number
LOT	Batch code
EC REP	Authorized representative in the European Community
	Indicates the entity importing the medical device into the local
	Non-ionizing electromagnetic radiation
MD	Medical device
UDI	Unique device identifier

4. Product Composition

This product is composed of the main body and cuff.

5. Intended Use / Instructions for Use

The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.

Intended users

1.Lay person or clinical professionals.

2.can read and understand the user manual.

Clinical benefit

Patients can monitor systolic pressure, diastolic pressure and pulse rate at home at any time, greatly reducing the number of visits to the hospital, reducing the risk of travel and improving the quality of patient's life.

6. Contraindication

Do not use this device if the patient’s condition meets the following contraindications, to avoid inaccurate measurements or injuries.

1.The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers,

and defibrillators.

2.Avoid taking measurement on the arm on the side of a mastectomy or lymph node clearance.

3.The device measures blood pressure using a pressured cuff. If the measuring limb suffers from injuries (for example open wounds) or under conditions or treatments (for example intravenous drip) making it unsuitable for surface contact or pressurization, do not use the device, to avoid worsening of the injuries or conditions.

4.Avoid taking measurements of patients with conditions, diseases, and susceptible to environment conditions that lead to incontrollable motions (e.g. trembling or shivering) and inability to communicate clearly (for example children and unconscious patients).

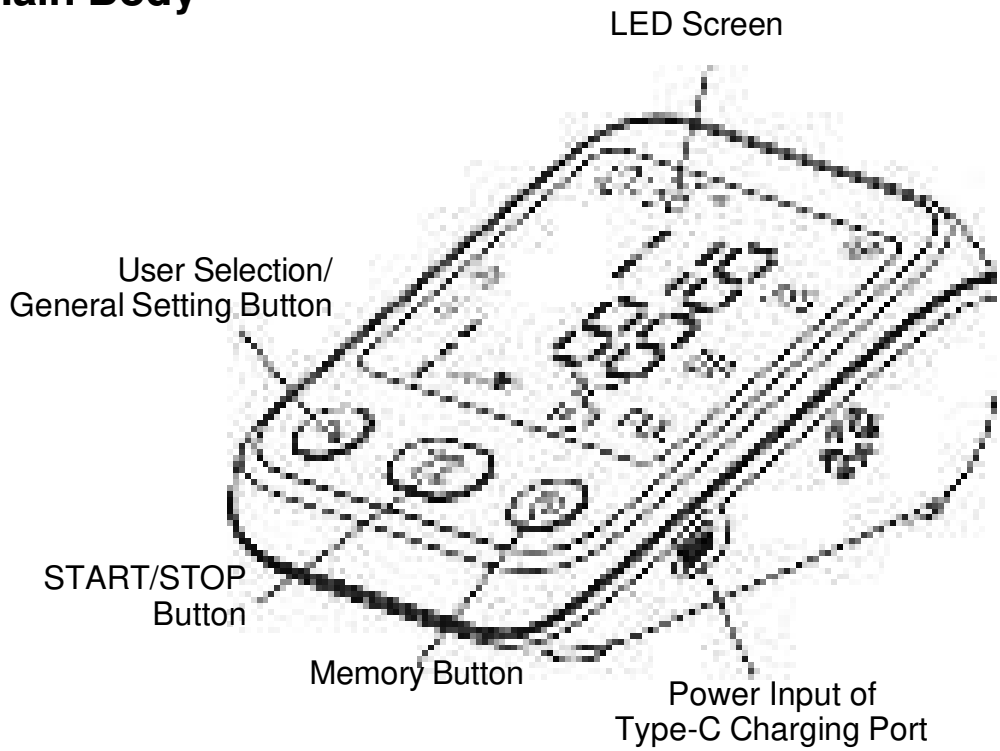
5.The device uses oscillometric method to determine blood pressure. The arm being measure should have normal perfusion.

The device is not intended to be used on a limb with restricted or impaired blood circulation. If you suffer with perfusion or blood disorders, consult your doctor before

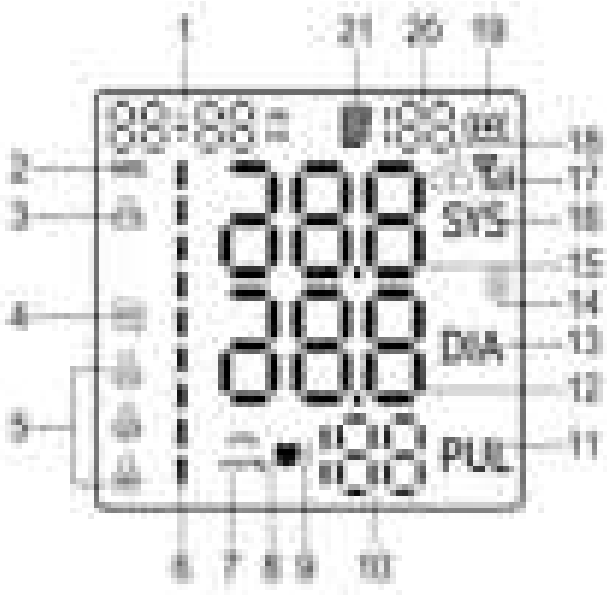
using the device.

7. Product Parts

(1) Main Body

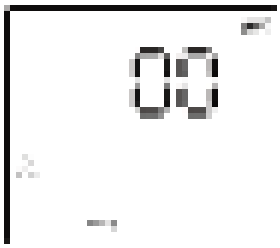


(2) Display Screen

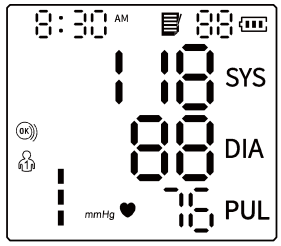


1. Date and Time
2. Average Value Icon
3. "Keep Still" Indication
4. "Cuff Worn" Detection
5. User Icon
6. Blood Pressure Indicator
7. Unit of Blood Pressure
8. Heartbeat Icon
9. Irregular Heartbeat Icon
10. Pulse Rate Value
11. Pulse Rate Icon
12. Diastolic Blood Pressure Value
13. Diastolic Blood Pressure Icon
14. sim card not working or no sim card
15. Systolic Blood Pressure Value
16. Systolic Blood Pressure Icon
17. Signal Strength Icon
18. Data Upload Icon
19. Battery Icon
20. Memory Number
21. Memory Icon

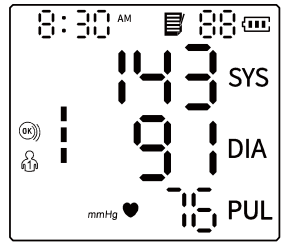
8. Blood Pressure Indication



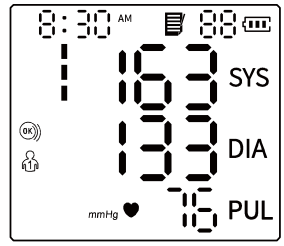
White for Standby



Green for Normal



Yellow for Mild High Blood Pressure or Hypotension



Red for High Blood Pressure

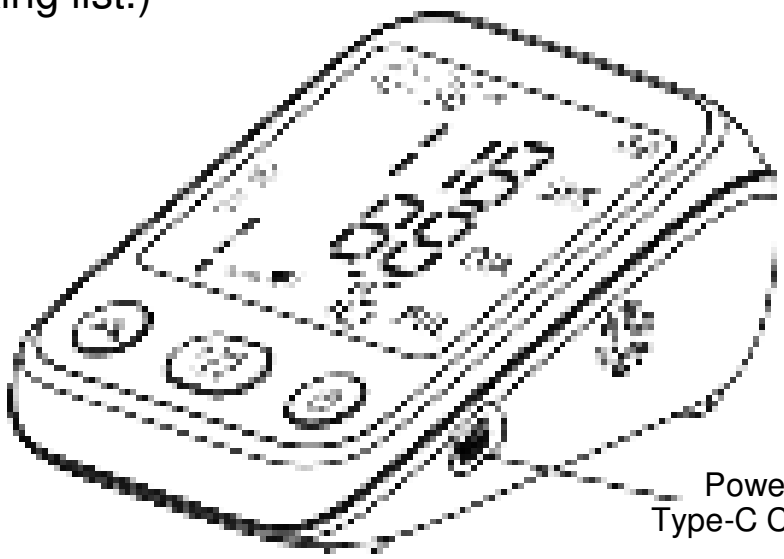
Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Color Display	Hierarchical Relationship
≥160	≥100	red	and (or)
140-159	90-99	yellow	and (or)
90-139	60-89	green	and (or)
<90	<60	yellow	and

Warning: When the blood pressure indicator is red, it means you are hypertension.
Please consult your physician immediately.

9. Power Connection

Type-C Connection for Power Supply

In addition to the batteries, the power can also be supplied by plugging into d.c. 5V/1A external power supply through a Type-C port. (The Type-C charging cable is not included inthe packing list.)



Power Input of
Type-C Charging Port

NOTE:

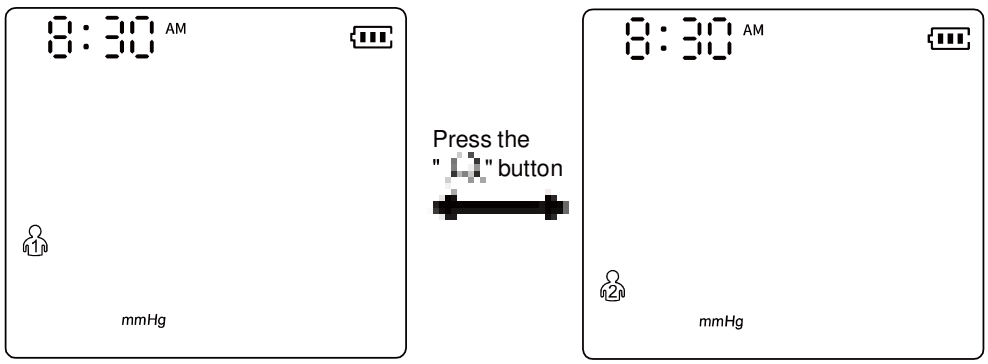
- The Type-C connector is intended to be used as a charging port for the device only.
- The adapter used should comply with the requirement of IEC 60601-1 standard,and the specifications must meet the requirements: input: AC 100~240V 50/60 Hz, output: DC 5V 1.0A. Other AC adapter may vary in output voltage and polarities and may represent a risk on your life and damaging the device.

- After fully charging the battery, if the working time of battery is shorter than before and you want to replace, do not try to replace the rechargeable battery by yourself. Please contact the manufacturer for replacement. Self-disassembly and replacement the battery may cause damage to the main unit and battery.
- When the product is not used for a long time, the battery will discharge slowly. In order to avoid battery damage due to low voltage for a long time, please charge the device for every three months.

10. Function Setting

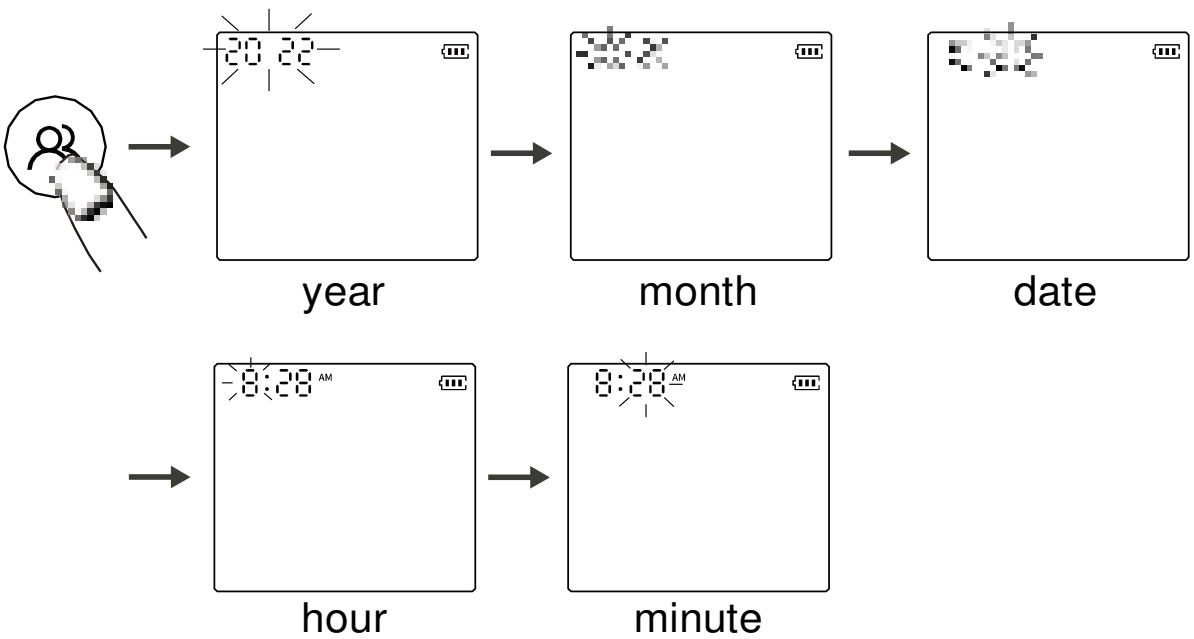
(1) User Selection

In the power-off mode, press the " " button to enter the user group selection interface. Then press the " " button again to switch and select user groups.



(2) Date And Time Setting

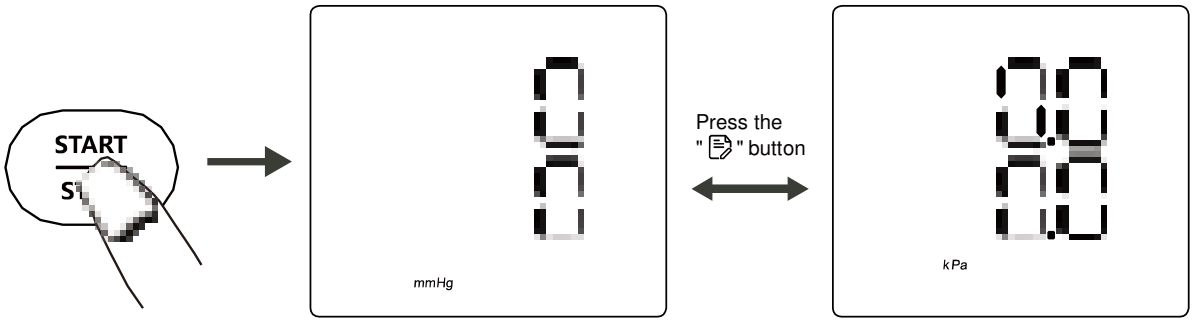
In the power-off mode, press the " " button for about 3 seconds to enter the date setting interface, and the "year" will flash. Press the " " button to adjust the year, and press the " " button to confirm the selection. When the year is set, it will automatically enter the month setting. Press the " " button to adjust the month, and press the " " button to confirm the selection. Follow the same steps to adjust the date/hour/minute.



(3) Unit Display Setting

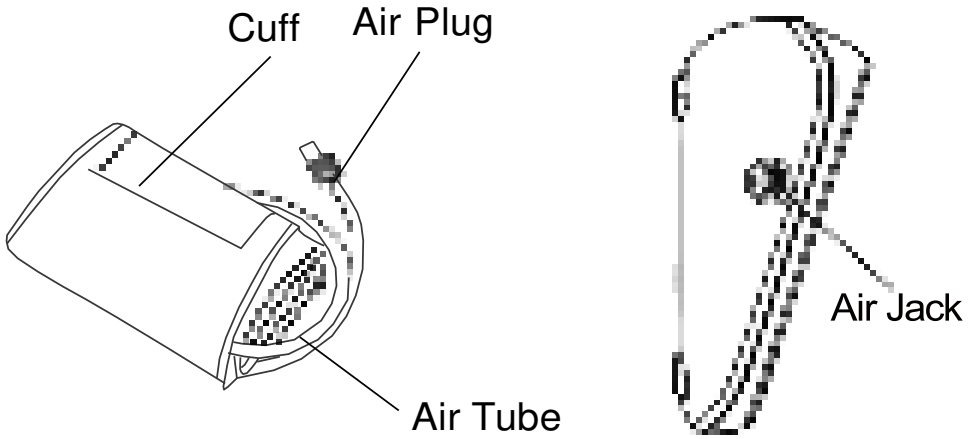
There are two units of blood pressure display, mmHg and kPa. The default unit is mmHg.

In the power-off mode, press the " START/STOP " button for about 5 seconds to enter the unit selection. Press the " " button to switch between mmHg and kPa, and then press the " " button to confirm the selection.

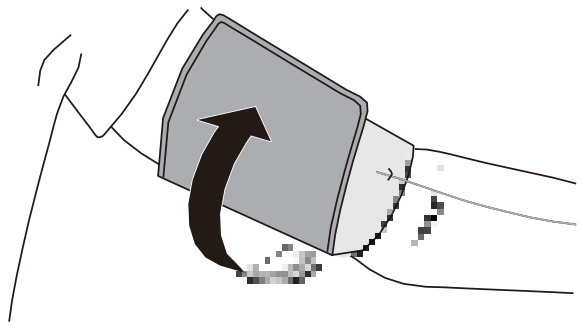


11. How To Apply The Arm Cuff

(1) Connect the arm cuff to the monitor by inserting the air plug into the air jack.

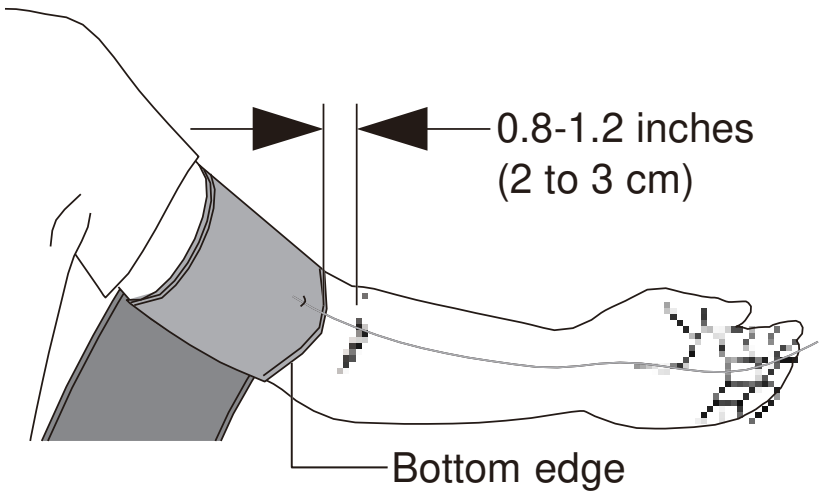


(2) Place your hand through the cuff loop. Pull the cuff until it reaches your upper arm.



Note:

The bottom edge of the arm cuff should be 0.8-1.2 inches (2-3cm) above the elbow. The air tube should be on the inside of your arm and aligned with your middle finger.



• Make sure that the air tube is positioned on the inside of your arm and wrap the cuff securely, so it can not move around your arm.

Note: Repeated measurement will result in blood congestion in the arm, which will affect the measurement result.
How to avoid blood congestion and ensure the repeated measurement is accurate?
You can raise the left hand and hold the fist several times, or take off the cuff and rest for at least 2-3 minutes before taking the measurement.

(3) Sitting correctly
To take a measurement, you need to be relaxed and comfortably seated in a room with a comfortable temperature.

• Sit in a comfortable chair with your back and arm supported.

• Keep your feet flat and your legs uncrossed.

• The arm cuff should be placed on your arm at the same level as your heart, with the arm resting comfortably on a table.

Warning: Do not kink the connecting tubing, as the resulting continuous cuff pressure can cause interference with blood flow and harmful injury to the patient.

12. How To Take Proper Measurements

(1) Preparation Before Measurement

-- Take off the clothes on the arm.

-- Always measure in the same arm (generally the left arm).

-- Remain still and keep quiet during the measurement.

-- Relax as much as possible and do not talk during measurement PROCEDURE.

-- Measure your blood pressure at about the same time every day.

-- Do not measure the blood pressure immediately after physical exercise or a bath. Rest for 20- 30 minutes before taking the measurement.

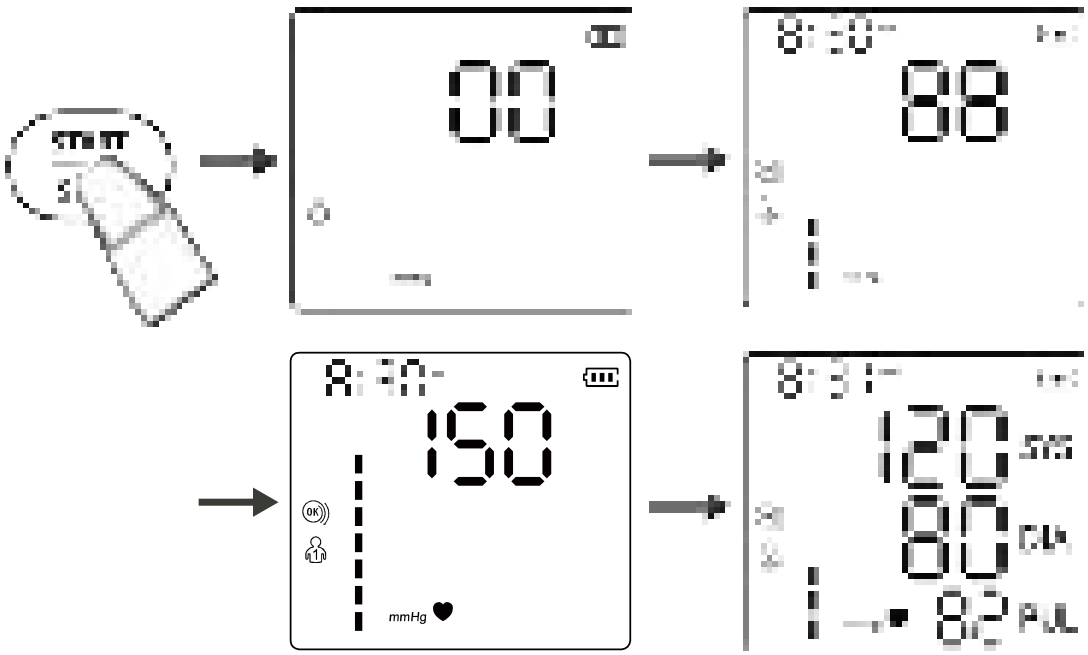
-- Measurements under the conditions listed below may affect results:

Having dinner, drinking wine, coffee, tea; doing sports; talking, being nervous, being in unsteady mood, bending forward, moving, room temperature dramatically changing; inside a moving vehicle, repeated and continuous measuring.

(2) Taking A Measurement

1) Fasten the arm cuff following the instruction of "How To Apply The Arm Cuff". Start the measurement after wearing the cuff correctly.

2) Press the " START/STOP " button. The monitor will start inflating for measurement and display " 00 ". Check the measured values after the measurement finished.



3）When the measurement is finished, take off the cuff and wait for the data to be uploaded to the background automatically. During the upload process, the " " icon flashes andthe signal strength icon " " is always on, and the memorygroup display area next to the battery will show the prompt code of the upload process according to the upload status. After upload successfully , the " " icon is always on, the signal strength icon " " is always on, the

memory group display area shows "P4", and the BPM will shuts down automatically; if the data upload fail, the BPM will automatically shut down after 5 minutes.

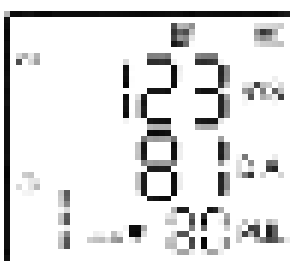
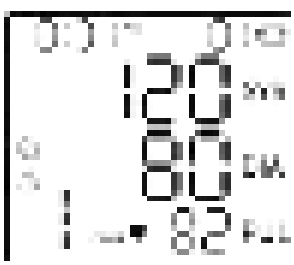
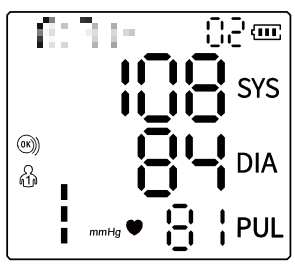
If the SIM card falls off or is loose, the no-card icon " " will always on.

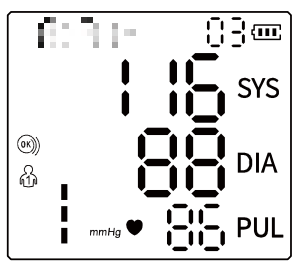
Note: If you feel uncomfortable during the measurement, press the " START/STOP " button immediately to stop the measurement. Please consult your doctor if unexpected readings areobtained.

(3) Memory Function

1) Each measured value is stored automatically under the appropriate user group.This device can store up to 199 sets of measurements for user 1 and user 2. Once the memory log is full, old values will be refreshed with new ones.

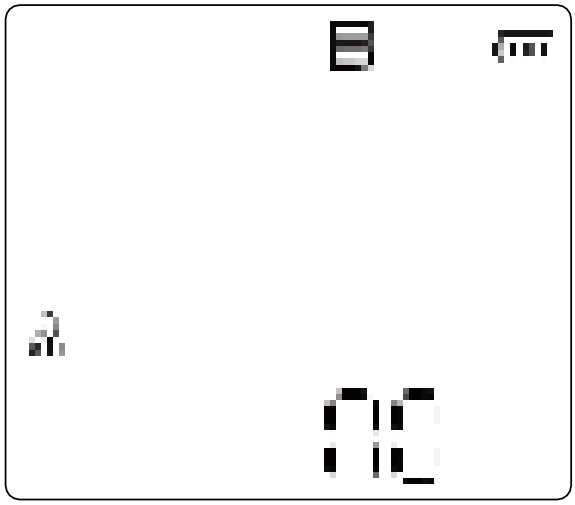
2) In the power-off mode, press the " " button once and the device will display the average value of the blood pressure measurements of the last 2 or 3 times. Press the " " button again, and the latest measured value will be displayed. Press the " " button again and the rest measured values will be displayed one by one.



3) Delete Memory

In the power-off mode, press the " " button to select the user group whose measured values need to be deleted. Press the " START/STOP " button to power off the device and press the " " button once to activate the screen. Then keep pressing the " " button for about 3 seconds to delete the memories of the selected user and the " " icon will appear on the screen.



(4) "Cuff Worn" Detection

The " " icon is always displayed on the screen when the cuff is wrapped correctly. If the " " icon is still flashing after 10 seconds from the start of the measurement, press the " START/STOP " button to power off the device,wear the arm cuff in the correct way and measure again.

(5) "Keep Still" Indication

The "  " icon flashes when you move your body or shake your arm during the measurement, which may cause incorrect measurement results. Please adjust your posture and measure again.

(6) Turn off the unit

Press  button to turn off the arm blood pressure monitor. The monitor automatically turns off after 1 minutes.

13. Specifications

Model	ARM-90B	
Display	LED screen	
Measuring Method	Oscillometric measurement	
Measuring Part	Upper arm	
Pneumatic Pressure Measuring Range	0~295 mmHg (0~39.3 kPa)	
Maximum Pressure Protection	295 mmHg (39.3 kPa)	
Measurement Range	Blood pressure value	SYS: 57~255 mmHg (7.6~34.0 kPa); DIA: 25~195 mmHg (3.3~26.0 kPa);
	Pulse rate	40~199 bpm
Accuracy of the cuff pressure	±3 mmHg(±0.4kPa)	

Accuracy of the pulse rate	±5 %		
Low Battery	When the power is lower than 4.0V±0.1V, the device will be turned off automatically.		
Power Source	800 mAh 3.7V Rechargeable lithium battery or or d.c. 5V/1A Type-C charging cable		
Memory	2 users x 199 memories + guest user without memories		
Dimension	130 mm (L) x 100 mm (W) x 60 mm (H)		
Screen Size	81.2mm (L) x 70.9mm (W) (4.2 inches)		
Cuff Size	22~42 cm (8.6~16.5 inches)		
Weight	About 234g		
Anti Electronic Shock Type	Internal Power Supply		
Auto Power-off	1 minute without operation		
Degree of protection	Type BF		
Operation Mode	Continuous operation		
Protection Against Harmful Ingress of Water or Particular Matter	IP21		
Monitor Service life	5 years		
Cuff Service life	10000 times		
Operating Environment	Temperature condition	5°C~40°C	If stored or used beyond

	Humidity condition	15%~90%RH	the designated temperature and humidity range, it will not be used properly
	Atmospheric condition	70kPa~106kPa	
Transportation and Storage Environment	Avoid strong impact, direct impact, exposure or rain during transportation. Store your monitor and other components in a clean, safe location. Remove the arm cuff from the monitor. Gently fold the air tube into the arm cuff. The device shall be stored indoors at the temperature of -20°C~55°C and the relative humidity of 10%~93%. Atmospheric condition: 70kPa~106kPa without corrosive gas and with good ventilation.		

The product was clinically investigated according to the requirements of ISO 81060-2.

Essential Performance

1. Measurement Range (Blood Pressure):

SYS: 57-255mmHg

DIA: 25-195 mmHg

Pulse rate: 40-199 bpm

2. Accuracy of the cuff pressure : ±3 mmHg (±0.4 Kpa)

Accuracy of the pulse rate:±5%

Note:The specified power supply should meet the

following condition:

Output voltage: DC 5V,
Output current:1000mA,
Class II
Comply with IEC 60601-1,

Provide at least two MOOP insulation between ac input and dc output,

Comply with US and Canadian deviation requirements.

4G:

Personal health information are not included in handling storage or transmission(health records ,health histories which include any individual identifiers such as picture, health insurance number, any identification ID or name).

The data that can be transferred over 4G are Device ID, measurement timestamp, measurement error code, systolic pressure, diastolic pressure, pulse rate, irregular pulse, measurement mode, and battery level.

14. Warnings and Cautions

Warnings

- No maintenance or servicing when using.
- Too frequent measurements can cause injury to the PATIENT due to blood flow interference.
- Consult with your physician before using this monitor on an 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 physician before using this monitor if you have had a mastectomy or lymph node clearance.
- Do not use the monitoring ME EQUIPMENT on the same limb simultaneously. This could temporarily cause loss of function or an inaccurate measurement.
- Please check whether the operation of the Arm blood pressure monitor leads to prolonged impairment of patient's blood circulation by observing the limb concerned.
- Please use component (eg. cuff) provided by manufacturer. Otherwise, the measurement accuracy will be affected.
- No modification of this equipment is allowed.
- To avoid strangulation, please keep the air tube and type-C charging cable away from the infants, toddlers and children.
- DO NOT use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- Do not leave the small parts where children can reach them. Children may swallow them. If a child accidentally swallows them, battery cover, please contact a doctor immediately.

- The cuff complies with the requirements of ISO 10993-5, ISO 10993-10, ISO 10993-23. But few sensitive people may have allergies.

Cautions

- Maintenance should be done by the manufacturer as suggested.
- When the ambient temperature is less than 5°C, please take the device to the place where the ambient temperature is between 5°C~40°C at least 1 hour; When the ambient temperature is higher than 40°C, please take the device to the place where the ambient temperature is between 5°C~40°C at least 2 hours.
- DO NOT use this monitor for infants, toddlers, children or persons who cannot express themselves.

- DO NOT take medicine based on readings from the device. Contact your physician for specific information about your blood pressure. The patient should not self-diagnose or self-medicate per measured results. Kindly adhere to the instructions of your physician or health provider.

- DO NOT use this monitor on an injured arm or an arm under medical treatment.

- DO NOT use the device while you are on an intravenous drip or blood transfusion.

- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pregnancy, pre-eclampsia or renal disease.

- NEVER diagnose or treat yourself based on the readings. ALWAYS consult with your physician.

- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders, because the cuff inflation can cause bruising.
- DO NOT use this monitor for any purpose other than measuring blood pressure and pulse rate.

- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.

- DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This may damage this monitor.

- DO NOT use this monitor in a moving vehicle such as in a car.

- DO NOT drop or subject this monitor to strong shocks or

vibrations.

- Do not use or store the monitor outside the manufacturer's specified conditions (extremely high or low temperatures and humidity), as this may affect the performance or cause inaccurate measurements.

- When the performance changes (such as: inaccurate measurement or abnormal display), please stop using it immediately and contact the sales service personnel in time.

15. Common Q & A on Blood Pressure

Q1: Why is the blood pressure value obtained at home lower than that obtained at the hospital?

- The blood pressure difference between home and hospital measurements is about 20 mmHg - 30 mmHg (2.7 kPa - 4.0 kPa). This is because individuals tend to be more relaxed at home than at the hospital.
- In addition, when the device is placed at a position over the heart, the blood pressure value tends to be much lower than it actually is. Ensure the device is positioned right at the heart level.

Q2: Why is the blood pressure value obtained at home higher than that obtained at the hospital?

- The anti-hypertensive drug might has lost its efficacy.

Kindly adhere to your doctor's instructions.

- The cuff might not be in the correct position. If the cuff is not placed right, no arterial pressure value will be obtained, and the blood pressure value might be much higher than it is. Therefore, properly position the cuff.
- The cuff is not tight enough. If the cuff is loose, the compression force might fail to transmit to the artery, causing the blood pressure value to be much higher than it is. Therefore, re-adjust and tighten the cuff further.
- The patient is not sitting correctly during the measurement. Slouching, tilting, bending, and sitting cross-legged are not encouraged while taking blood pressure measurements due to increased abdominal pressure or the arm position being below the heart. Kindly take readings in the correct posture.

Q3: When can I obtain better measurements?

- Measurements are best taken in the mornings right after you urinate or when your mind and body are stable. We recommend taking readings at the same time of the day, every time.

Q4. Why the blood pressure value measured each time is different?

1) When systole each time, the blood pressure will change tosome extent. For example, a person with the pulse of 70beats per minute will have 100,800 blood pressure changes every day.

Because the blood pressure is constantly changing, it is difficult to obtain the correct blood pressure value by measurement only once. Please make measurement for 2~3 times. The first measurement will generally be higher due to nervousness or inadequate preparation, and then when the second measurement, the nervous emotion will be slightly alleviated, so generally, the second measurement will be5mmHg-10mmHg (0.7kPa-1.3kPa) lower than the first time. This will be more obvious for those with higher blood pressure.

--When continuous measurement, please note that: There might be extravasated blood because the arm is compressed, resulting that the fingertip blood does not flow smoothly, If you continue the measurement in case of extravasated blood, you cannot obtain the correct measured value. Loosen the arm band, raise your hand over the head and grasp and stretch your left and right palms for 15 times repeatedly. Then the extravasated blood can be dis solved and you can continue the blood pressure measurement

2) Cuff position and twining method. The measured value varies with the cuff size. Particularly, if the cuff is twined round the elbow, you cannot obtain the correct measured value.

--Please use the correct cuff twining method for

measurement. The arm circumference range of the enclosed cuff is 22~42 cm (center of the upper arm). If the model is inconsistent, please purchase separately.

16. Abnormal Phenomena and Handling

If the measurement is abnormal, any of the following symbols may appear. Kindly use the recommended method for measurement.

Errors	Cause/Solution
Er U	The pressure cannot reach 30 mmHg (4 kPa) in 12 seconds.
Er H	The inflation reaches 295mmHg, and it deflates automatically after 20ms.
Er 1	The pulse rate is not detected correctly.
Er 2	Too much disturbance (Move, talk, or magnetic disturbance during a measurement).
Er 3	The measurement result is abnormal.
Er 23	SYS value reads lower than 57mmHg.
Er 24	SYS value reads higher than 255mmHg.
Er 25	DIA value reads lower than 25mmHg.
Er 26	DIA value reads higher than 195mmHg.

* Troubleshooting

Anomaly	Possible Faulty	Solution
Failure to power on	Whether the power is insufficient	Replace the batteries or insert the Type-C charging cable for power supply
	Whether the positive and negative poles of the battery are installed reversely	Install the batteries correctly
No pressurizing	Whether the air tube plug is inserted tightly	Insert the air tube plug firmly into the jack
	Whether the air tube is broken or leaked	Please contact the dealer to replace with a new cuff
Unable to measure due to the display error	Whether the arm is moved when pressurization	Keep your arm and body still
	Whether you talk during the measurement	Keep quiet while measuring the blood pressure
Air leakage of the cuff	Whether the cuff is twined too loose	Please tighten the cuff
	The airbag of the cuff is ripped	Please contact the dealer to replace with a new cuff

 If the blood pressure still cannot be measured after trying the above-stated solutions, please contact the dealer. DO NOT attemptto disassemble the device by yourself.

17. Cleaning and Disinfection

1) Cleaning

The device can be cleaned with a soft, clean cloth dampened with a small amount of neutral detergent or water.

It is suggested to clean the monitor before and after each use. Complete the cleaning in 3min each time. The number of repeated cleaning each time shall not exceed 3 times.

 Do not use any corrosive cleaning agent. When cleaning, be careful not to immerse any part of the monitor to avoid liquid flow into the instrument.

2) Disinfection

Recommended Disinfecting Agent

75% medical alcohol

Steps:

- Carefully wipe the device with a soft, clean cloth dampened with a small amount of the above disinfectant, and dry immediately with a soft, clean, dry cloth.
- The body of the device can also be cleaned with a soft, clean cloth dampened with a small amount of 75% medical

alcohol for disinfection.

 Do not disinfect through methods like high-temperature steam or ultraviolet radiation. These might damage the device and reduce its service life.

It is suggested to disinfect the monitor before and after use each time. Each time of disinfection shall be completed within 1min. The number of repeated disinfection each time shall not exceed 2 times.

3) Disposal

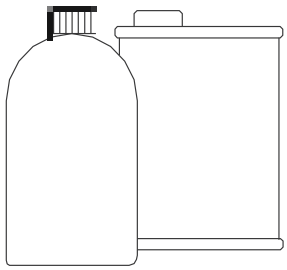
Dispose of the monitor, other components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

Notes

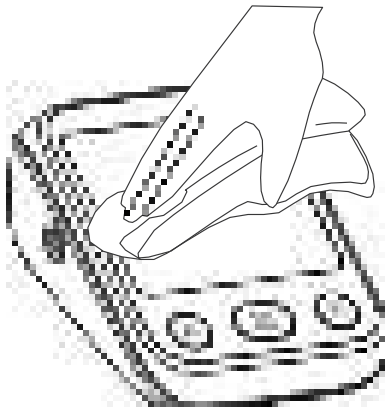
- Do not bend or crease the air tube excessively.
- Do not store the monitor or its components:

- if the monitor or its parts is wet.
- in locations with extreme temperatures, humidity, direct sunlight, dust, or corrosive gases.
- in areas with a high risk of vibrations or shocks.

18. Upkeep and Maintenance



Water or neutral detergent



- Always keep the surface of the device clean and tidy, helpful to prolong its service life.
- If the device is dirty, please wipe with a dry soft cloth. If the dirt cannot be eliminated easily, wipe with a soft cloth stained with water or neutral detergent, and then dry with a dry cloth.
- We suggest to calibrate the monitor once a year at least. Please contact manufacturer or agent if you need.

Warning:

Do not allow water or other liquids to flow into the device.

The arm pressure monitor should not no longer be reused when liquid enter and damage the device and cuff.

19. Appendix 1 EMC Information

Guidance and manufacturer's declaration - Electromagnetic emission		
The Arm Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Arm Blood Pressure Monitor should assure that it is used in such an environment.		
Emissions	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Arm Blood Pressure Monitor 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	The Arm Blood Pressure Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	N.A.	
Voltage fluctuations/flicker emissions IEC61000-3-3	N.A.	

Guidance and manufacturer's declaration - Electromagnetic immunity		
The Arm Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the arm Blood Pressure Monitor should assure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
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
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
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines NA 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV, differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV, differential mode N/A
Voltage dips, short interruptions and voltage variations on power supply input lines 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 cycles; Single phase: at 0°. 0% UT; 250 / 300 cycle	0% UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT; 1 cycle and 70% UT; 25/30 cycles; Single phase: at 0°. 0% UT; 250 / 300 cycle
Power frequency Magnetic field IEC 61000-4-8	30A/m, 50/60Hz	30A/m, 50/60Hz
Conduced RF IEC61000-4-6	3V signal input/output; 0,15MHz-80MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 2Hz	3V signal input/output; 0,15MHz-80MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 2Hz

Radiated RF IEC61000-4-3	10 V/m 80 MHz - 2,7 GHz 80 % AM at 2 Hz	10 V/m 80 MHz - 2,7 GHz 80 % AM at 2 Hz
NOTE: UT is the a.c. mains voltage prior to application of the test level		

Guidance and manufacturer's declaration - electromagnetic Immunity

The Arm Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Arm Blood Pressure Monitor should assure that it is used in such an environment .

Radiated RF0-4-3 (Test specifications for ENCLOSURE- PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Max. Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28	28
	710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	810 870 930	800-960	GSM 800/900, TETRA 800, DEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28

	1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							
	2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
	5500							
	5785							

Guidance and manufacturer's declaration - electromagnetic Immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Moduation	IEC 60601-1-2 Test Level (A/m)	Compliance level (A/m)
	30 kHz	CW	8	8
	134.2 kHz	Pulse modulation 2.1 kHz	65	65
	13.56 MHz	Pulse modulation 50 kHz	7.5	7.5

Warning:

- Use of accessories, transducers and cables 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 res ult in improper operation.
- Portable RF-communications equipment (including peripherals like antenna cables and external antennas) should be kept at least 30cm (12 inches) from the device and its parts to prevent degradation of the monitor.
- Do not use this device adjacent to or stacked on other equipment to prevent improper functioning. If such use is necessary, all accessories involved must be checked for normal operation.
- Do not use this device within regions of active HF-surgical equipment or RF-shielded room of an ME system for magnetic resonance imaging, where EM disturbances may be high.

FCC Caution:

Part 15.21

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

Part 15.19

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.

FCC RF Radiation Exposure Statement:

This device complies with RF specifications when the device used at 4.7cm from the body.

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Notice:

If users or patients have occurred any serious incident that relation to the device, please report to manufacturer and the competent authority of the Member State in which you are established.

Code	Information
P0	Initial display
P1	Startup, Initialized atcmd
P2	Network connection ok
P3	Data uploading
P4	Data uploaded successfully, waiting for new data
E1	Communication failure
E2	Sim card cannot be read
E3	Data upload error
E4	TCP connection failed
E5	Signal strength is weak
E6	Network registration failed

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