Arm Blood Pressure Monitor
User Manual

Model: ARM-30Y
Manual version:A0
Issue date:2024-01

Table of Contents

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

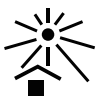
Before use, please open the package carefully and check whether all the parts are available according to the following packing list and whether the parts are damaged during Transportation, Then install and operate in strict accordance with the user manual.

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. Safety Precautions

The warnings and illustrations shown in the manual are intended to enable you to use the product safely and correctly, thus preventing harm to you and others, specific meanings of which are shown as follows:

	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 greater; 1 Protection against vertically falling water drops
CE 0123	CE mark
	Manufacturer

	Date of manufacture
SN	Serial number
LOT	Batch code
EU REP	Authorized representative in the European Community
RoHs	RoHS mark
MD	Medical device
UDI	Unique device identifier
	Indicates the entity importing the medical device into the local

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

The traditional auscultation method needs to learn to determine the level of blood pressure through the sound, it

has high requirements for the user, requiring the user to accurately hear the Kirknoise and make a judgment, and this method judges the value by human vision and hearing, with subjective factors, unless professional doctors, it is difficult for ordinary people to obtain accurate blood pressure values, and it is not very convenient to carry the stethoscope. However,the arm blood pressure monitor based on the principle of non-invasive oscillometric method is easy to operate, and the reading is obvious and intuitive. 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 qualityof 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

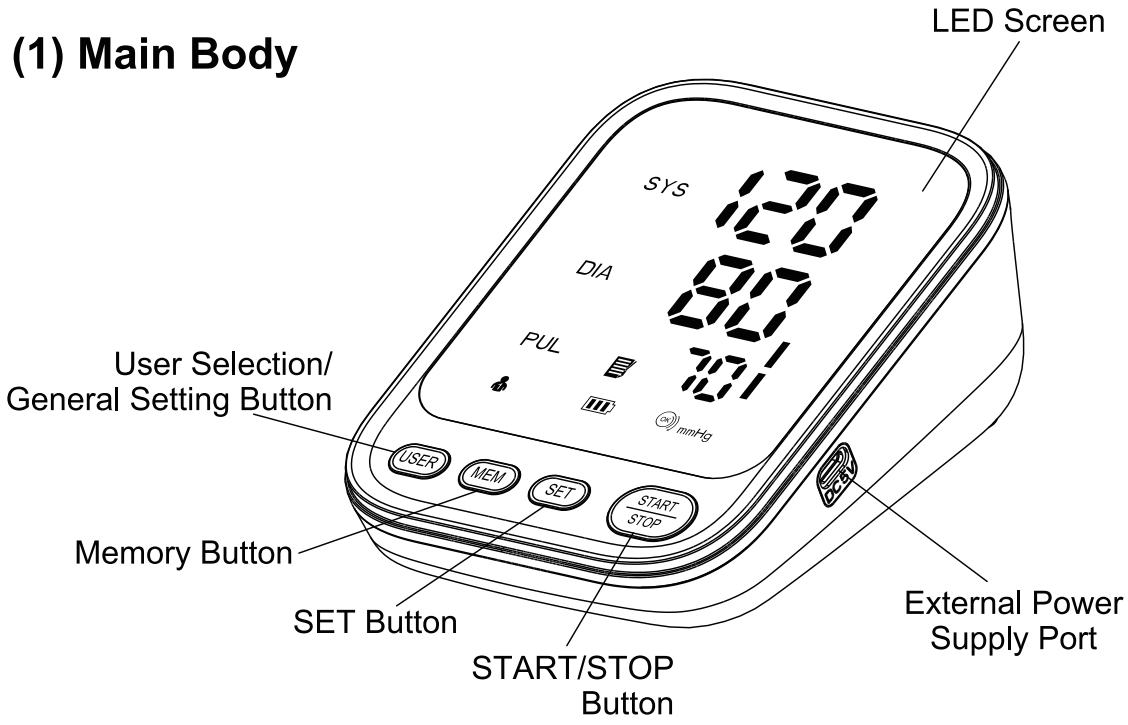
intravenous drip) making it unsuitable for surface contact or pressurization, do not use the device, to avoid worsening of the injuries or conditions.

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).

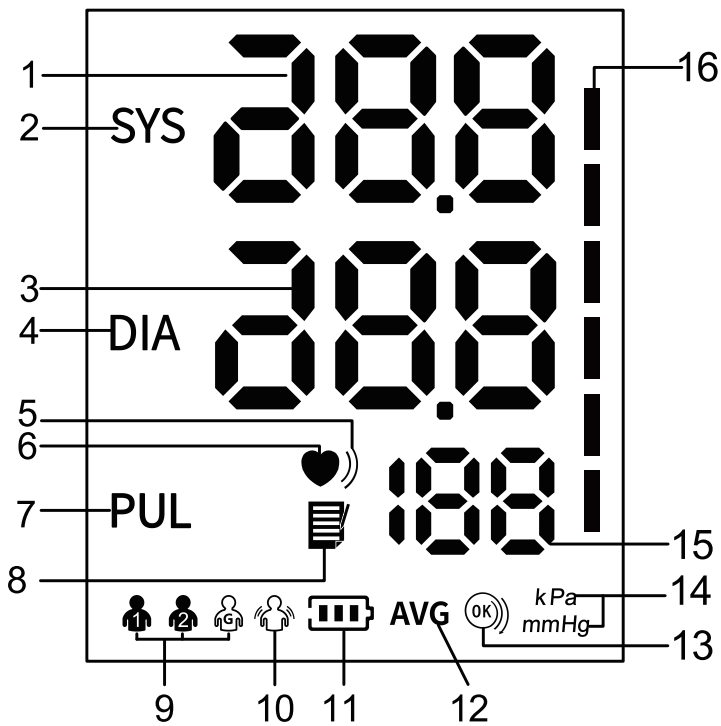
5. The device uses oscillometric method to determine blood pressure. The arm being measure should have normal perfusion. The device is not intended to be used on a limb with restricted or impaired blood circulation. If you suffer with perfusion or blood disorders, consult your doctor before using the device.

7. Product Parts

(1) Main Body



(2) Display Screen



1.Systolic Blood Pressure Value
2.Systolic Blood Pressure Icon
3.Diastolic Blood Pressure Value
4. Diastolic Blood Pressure Icon
5. Irregular Heartbeat Icon
6. Heartbeat Icon
7. Pulse Rate Icon
8. Memory Icon
9. User Icon
10. "Keep Still" Indication
11. Battery Icon
12. Average Value Icon
13. "Cuff Worn" Detection
14. Unit of Blood Pressure
15. Pulse Rate Value
16. Blood Pressure Indicator

8. WHO Blood Pressure Indicator

Color Display		BP Classification	Systolic Blood Pressure(mmHg)	Diastolic Blood Pressure(mmHg)
	Red	Serious hepertension	≥180	≥110
	Red	Moderate hypertension	160-179	100-109
	Red	Mild hypertension	140-159	90-99
	Orange	High normal value	130-139	85-89
	Green	Normal blood pressure	120-129	80-84
	Green	Optimal blood pressure	＜120	＜80

Warning:

When the blood pressure indicator is red, it means you are hypertension.

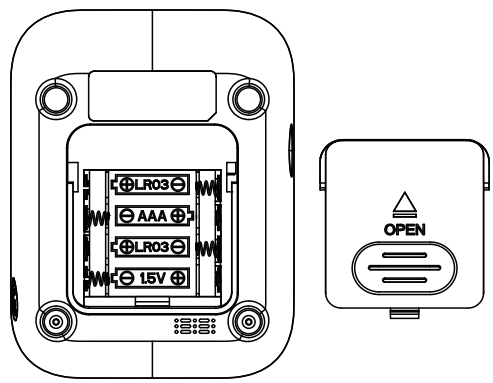
Please consult your physician immediately.

9. Power Connection

(1) Install The Batteries

1) Open the battery cover according to the method shown in the figure.

2) Place 4 AAA batteries in the battery compartment, and pay attention to the electrode indication of the batteries. Install the battery as indicated in the picture.



Warning: Remove the batteries if you do not intend to use the device for a long time (over 3 months).

(2) 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 power supply line is not included in the packing list.)

NOTE:

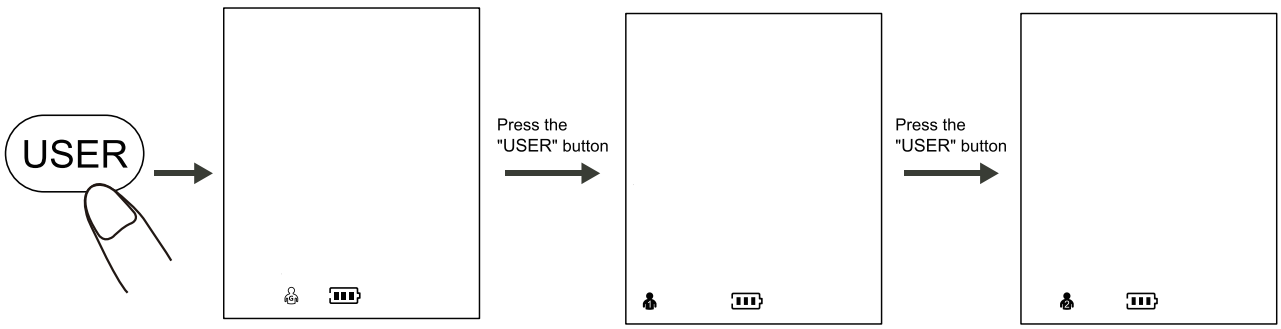
● The adapter access function is suitable for temporary use when you don't have suitable AAA batteries around.

The adapter 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.

10. Function Setting

(1) User Selection

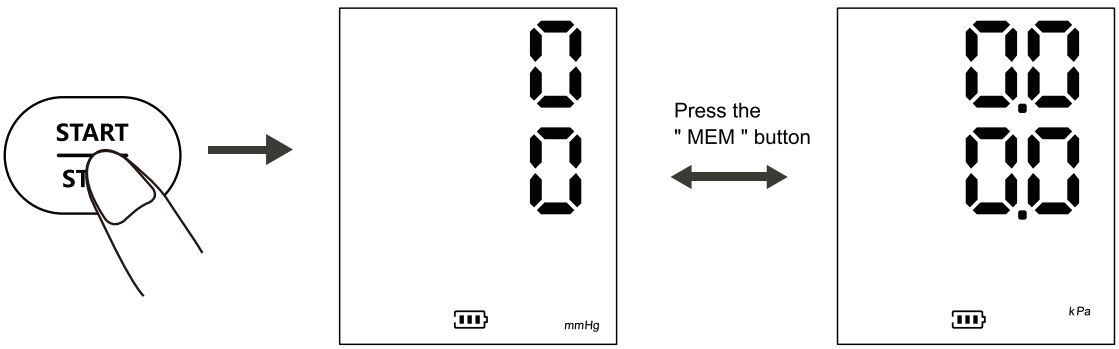
In the power-off mode, press the " USER " button to enter the user group selection interface. Then press the " USER " button again to switch and select user groups.



(2) Unit Display Setting

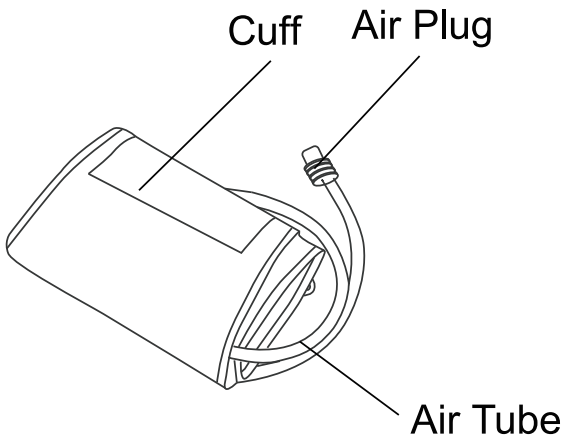
There are two units of blood pressure display, mmHg and kPa. The default unit is mmHg.

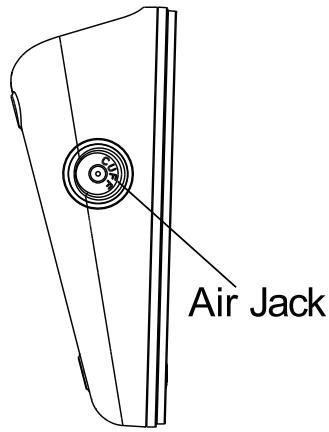
In the power-off mode, press the " START/STOP " button for about 5 seconds to enter the unit selection. Press the " MEM " button to switch between mmHg and kPa, and then press the " START/STOP " button to confirm the selection.



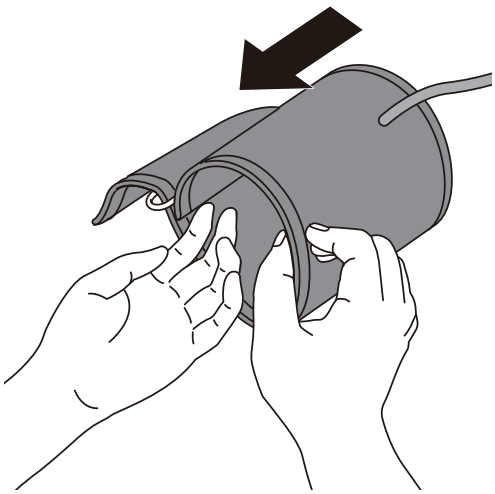
11. How To Apply The Arm Cuff

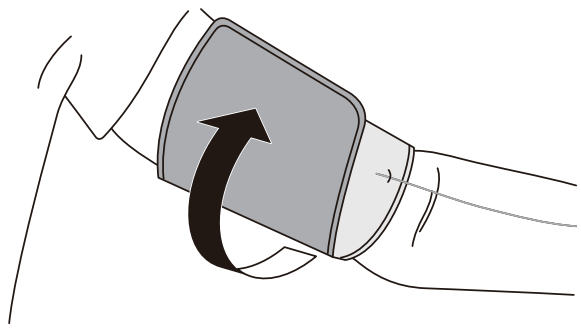
(1) Connect the arm cuff to the monitor by inserting the air plug into the air jack.





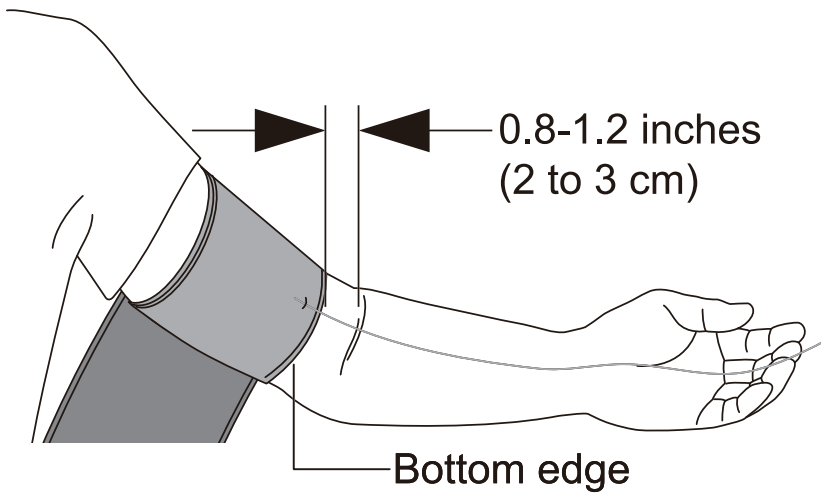
(2) Place your hand through the cuff loop. Pull the cuff until it reaches your upper arm.





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.

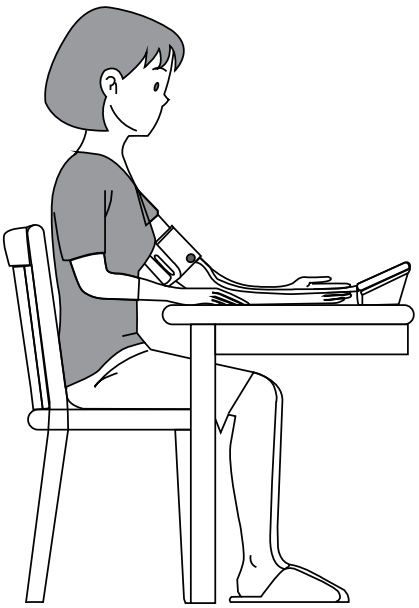


• Make sure that the air tube is positioned on the inside of your arm and wrap the cuff securely, so it can not move around your arm.

Note: Repeated measurement will result in blood congestion in the arm, which will affect the measurement result.
Be careful not to rest your arm on the air tube.
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. Place your arm on the table.



• 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.

-- 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.

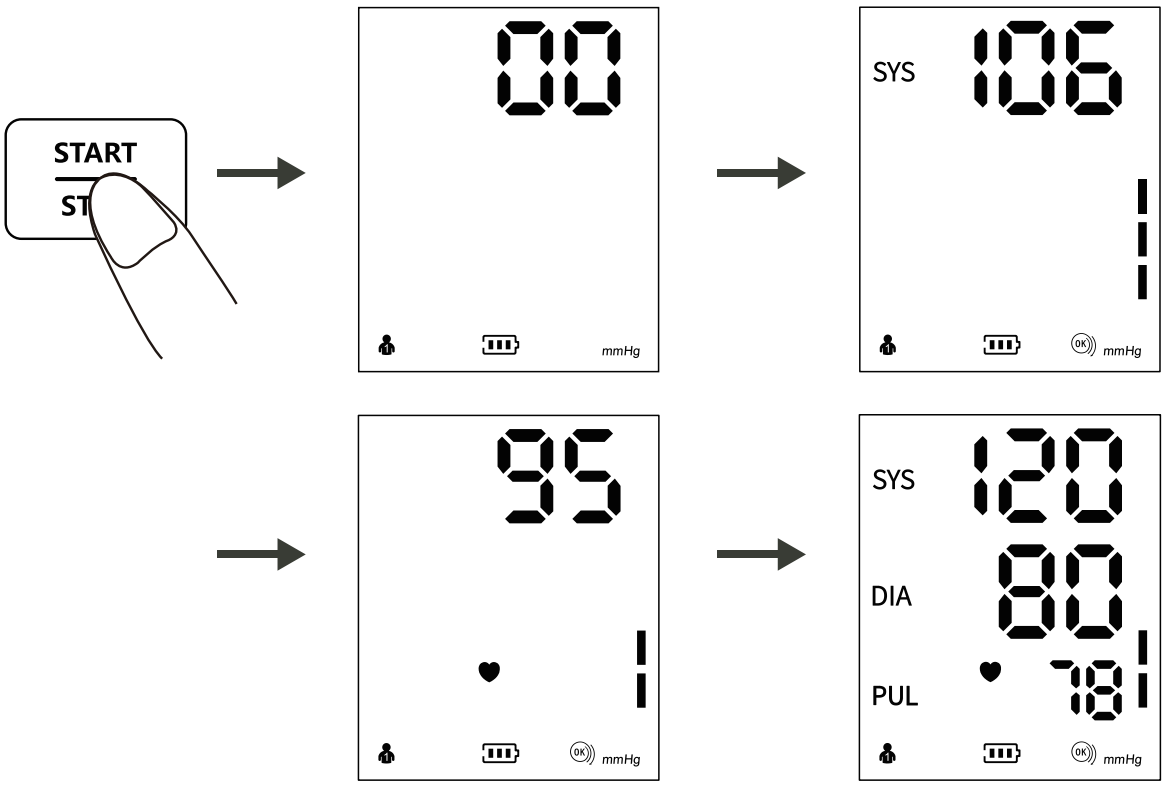
-- Measurements under the conditions listed below may affect results:

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 measuing.

(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.



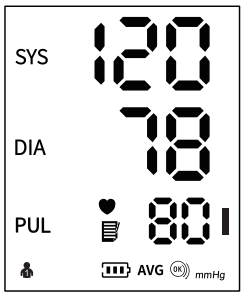
Note: If you feel uncomfortable during the measurement, press the " START/STOP " button immediately to stop the measurement. When the air pressure is filled to a certain value, the value on the display screen will slowly drop at a certain speed and the heartbeat symbol will flash. After the measurement is completed, the systolic pressure diastolic pressure and pulse measurements will be displayed on the screen.

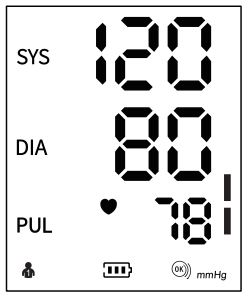
Note: Consult your doctor if unexpected readings are obtained

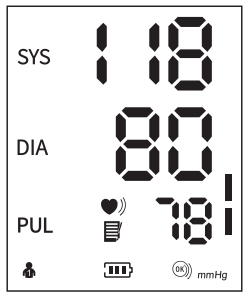
(3) Memory Function

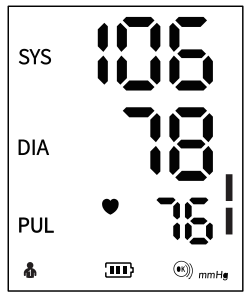
1) Each measured value is stored automatically under the appropriate user group. This device can store up to 199 sets of measurements for user 1 and user 2. Once the memory log is full, old values will be refreshed with new ones.

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



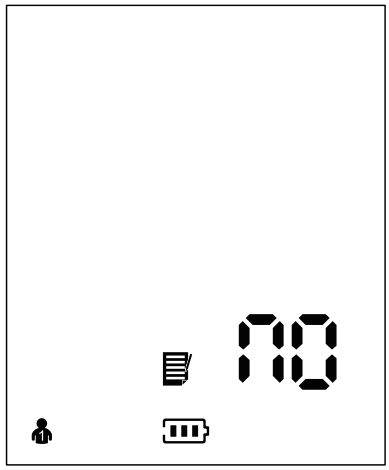






3) Delete Memory

In the power-off mode, press the " USER " 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 " MEM " button once to activate the screen. Then keep pressing the " MEM " button for about 3 seconds to delete the memories of the selected user and the "00" icon will appear on the screen.



(4) "Cuff Worn" Detection

The " OK " icon is always displayed on the screen when the cuff is wrapped correctly. When the cuff is too loose, the " OK " icon will always flash to remind you. If the " OK " icon is flashing, please press the " START/STOP " button to stop the measurement.

(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) Irregular Heartbeat Indication

The " ♥ "heartbeat icon flashes once a pulse is detected during the measurement.

The " ♥ " icon is displayed with the reading only if an irregular heartbeat is detected.

(7) Turn off the unit

Press [START/STOP] button to turn off the Arm blood pressure monitor. The monitor automatically turns off after 1 minutes.

13. Specifications

Model	ARM-30Y	
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	Blood pressure value	±3 mmHg (±0.4 kPa)
	Pulse rate	±5%
Low Battery	When the power is lower than 4V±0.1V, the device will be turned off automatically.	
Power Source	4*AAA batteries or d.c. 5V,1A power supply line	

<table>
<tr><td>Memory</td><td colspan="3">2 users x 199 memories + guest mode</td></tr>
<tr><td>Dimension</td><td colspan="3">140.8 mm (L) x 110 mm (W) x 61 mm (H)</td></tr>
<tr><td>Screen Size</td><td colspan="3">73 mm (L) x 88 mm (W)
(4.5 inches)</td></tr>
<tr><td>Cuff Size</td><td colspan="3">22~42 cm (8.6~16.5 inches)</td></tr>
<tr><td>Weight</td><td colspan="3">About 265g (without batteries)</td></tr>
<tr><td>Auto Power-off</td><td colspan="3">1 minute without operation</td></tr>
<tr><td>Anti Electronic Shock Degree</td><td colspan="3">Type BF</td></tr>
<tr><td>Operation Mode</td><td colspan="3">Continuous operation</td></tr>
<tr><td>Protection Against Harmful Ingress of Water or Particular Matter</td><td colspan="3">IP21</td></tr>
<tr><td>Monitor Service life</td><td colspan="3">5 years</td></tr>
<tr><td>Cuff Service life</td><td colspan="3">10000 times</td></tr>
<tr><td>Protection Against Electric Shock</td><td colspan="3">Internally powered ME equipment (When using only batteries)
Class II ME equipment (if equipped with AC adapter)</td></tr>
<tr><td rowspan="3">Operating Environment</td><td>Temperature condition</td><td>5°C~40°C</td><td rowspan="3">If stored or used beyond the designated temperature and humidity range, it will not be used properly</td></tr>
<tr><td>Humidity condition</td><td>15%~90%RH</td></tr>
<tr><td>Atmospheric condition</td><td>70kPa~106kPa</td></tr>
</table>

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 packaged Blood Pressure Monitor shall be stored indoors at the temperature of -20℃~55℃ 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 requirement 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:
Blood Pressure: ±3 mmHg (±0.4 Kpa)
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 MOPP insulation between ac input and dc output,
Comply with US and Canadian deviation requirements.

Statement: “The ARM-30Y of Arm Blood Pressure Monitor was tested according to the recommendations of Technical Report IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity; performance of medical electrical equipment and medical electrical systems."

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 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.

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

⚠ Caution

●Do not perform measurements more frequently than necessary.Due to the interference of blood flow, some bruising may occur.

● 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 the device while you are on an intravenous drip or blood transfusion.

● 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.

● Make sure that the cuff is not placed on an arm in which the arteries or veins are undergoing medical treatment, e.g. intravascular access or intravascular therapy,or an arteriovenous(AV)shunt.

● 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.

● 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 further. 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 is lower than 57mmHg.
Er 24	SYS value is higher than 255mmHg.
Er 25	DIA value is lower than 25mmHg.
Er 26	DIA value is higher than 195mmHg.

* Troubleshooting

Anomaly	Possible Faulty	Solution
Failure to power on	Whether the power is insufficient	Replace the batteries or insert the power supply line 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 attempt to 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 once every week. Complete the cleaning in 3min each time. The number of repeated cleaning each time shall not exceed 3 times.

⚠ Do not use corrosive cleaning agents, 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:

1) 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.
2) 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.

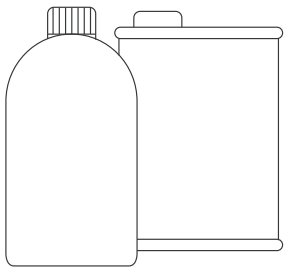
Notes

● Do not bend or crease the air tube excessively.

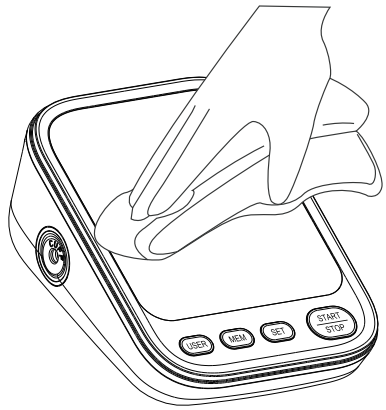
● Do not store the monitor or its components:

- 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
Electrical fast transient/burst IEC 61000-4-4	±1 kV signal input/output 100 kHz repetition frequency	±1 kV signal input/output 100 kHz repetition frequency
Surge IEC 61000-4-5	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable
Power frequency Magnetic field IEC 61000-4-8	30A/m, 50/60Hz	30A/m, 50/60Hz
Conducted 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 1845 1970	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
	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 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9

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

Statement: "The ARM-30Y of Arm Blood Pressure Monitor was tested according to the recommendations of Technical Report IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity; performance of medical electrical equipment and medical electrical systems."

Warning:

● Use of this equipment adjacent to or stacked with other equipment should be avoided because 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.

● 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 result in improper operation."

●Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

●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 the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Notice

If you think you or someone in your family has experienced a serious reaction to a medical product, please report to manufacturer and the competent authority of the Member State in which you are established.

EU REP

Share Info GmbH
Am Schulzentrum 12,41564 Kaarst,Germany
Tel:0049 179 5666 508
E-mail: EU-Rep@share-info.com

Shenzhen AOJ Medical Technology Co., Ltd.
Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Email: info@aojmedical.com
Website: www.aojmedical.com
Tel: 86-755-2778 6026
Made in China