

ArmBloodPressureMonitor

UserManual



Model: ARM-30A+

Table of Contents

1. Unpacking Inspection	1
2. Packing List	1
3. Symbol Definition	2
4. Product Composition	4
5. Intended Use / Instructions for Use	4
6. Contraindication	5
7. Product Parts	6
8. Four-Color Backlit Display	7
9. Preparation	8
10. Function Setting	10
11. How to Take Proper Measurements	13
12. Warnings and Cautions	19
13. Common Q&A on Blood Pressure	23
14. Abnormal Phenomena and Handling	25
15. Cleaning and Disinfection	27
16. Upkeep and Maintenance	30
17. Specifications	30
18. Appendix 1 EMC Information	34

Thank you for purchasing this Arm Blood Pressure Monitor. The monitor can be used and store measurement results for two users. It uses the oscillometric method of blood pressure measurement. This means this monitor detects your blood movement through your brachial artery and converts the movements into a digital reading. The device can be used in home care 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 manual.











2. Packing List

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

3. Symbol Definition

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

RoHS	RoHSmark
	CEmark
	Manufacturer
	Date of manufacture
	Serial number
	Batch code
	Authorized representative in the European Community ,
	Medical device
	Non-ionizing electromagnetic radiation
	Indicates the entity importing the medical device into the local
	Unique device identifier

4 . ProductComposition

Thisproductiscomposedofthemainbodyandcuff.

5 .IntendedUse/InstructionsforUse

TheArmBloodPressureMonitorisintendedtomeasurethe systolicpressureanddiastolicpressure, aswellasthepulse rateofadultpersonvianon- invasiveoscillometrictechnique atmedicalfacilitiesorathome.

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 monitorbased 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 quality of patient's life.

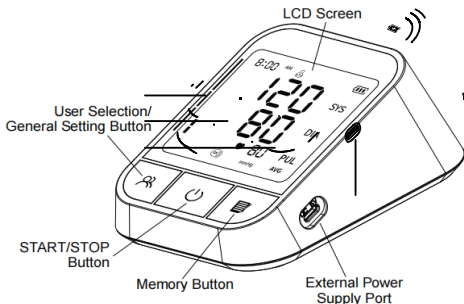
6. Contraindication

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

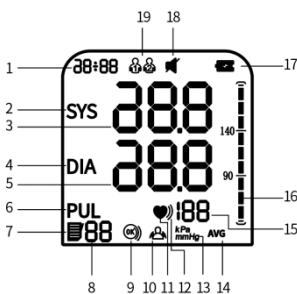
1. The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, and defibrillators.
2. Avoid taking measurement on the arm on the side of a mastectomy or lymph node clearance.
3. The device measures blood pressure using a pressured cuff. If the measuring 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 uncontrollable 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) Mainbody

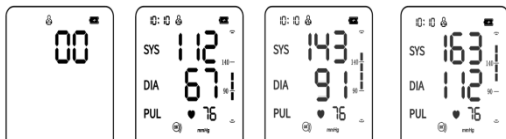


(2) Displayscreen



1. Date and Time
2. Systolic Blood Pressure Icon
3. Systolic Blood Pressure Value
4. Diastolic Blood Pressure Icon
5. Diastolic Blood Pressure Value
6. Pulse Display
7. Memory Icon
8. Memory Number
9. Detection for Cuff Wrapping Icon
10. Indication for Wrong Operation
11. Heartbeat Icon
12. Irregular Heartbeat Icon
13. Unit of Blood Pressure
14. Average Value Icon
15. Pulse Rate Value
16. Blood Pressure Classification Indication
17. Low Battery Icon
18. Voice Off Icon
19. User Icon

8. Four-Color Backlit Display



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	or
140- 159	90-99	yellow	or
90- 139	60-89	green	or
<90	<60	yellow	and

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

Please consult your physician immediately.

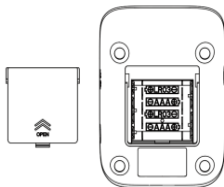
9.Preparation

(1)Installthebattery

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 right under this sentence.



(2) Battery replacement

Warning: If the product won't be used for a long time (over 3 months), please take out the batteries.

(3) Type C connection for power supply (The cable is optional)

The product power can be supplied by plugging into d.c. 5V, 1A external power supply through a Type C interface.



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- The

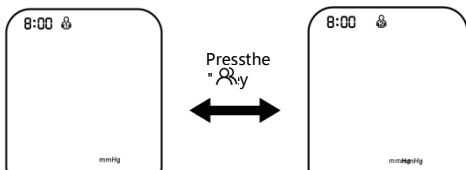
you don't have suitable AAA batteries around.

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) Usermode

In standby mode, press the " " button  to enter the user group selection interface. Then press the " " button  to switch and select user groups.





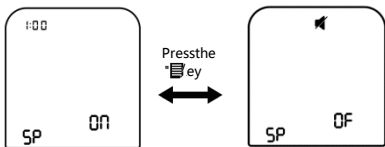
(2) Year/month/date setting

In standby mode, press " " for  3 seconds to enter the date setting, and "year" will flash. Press " " to adjust  to the desired year, and then press " " to confirm  selection. When the "year" is set, it will automatically enter the month setting. At this time, the "month" icon will flash. You can switch to the desired value by pressing the " " button.  Follow the same steps to set "date", "hour", and "minute".



(3) Voiceon/ offsetting(forvoiceversiononly, optionalfunction)

1) Afterthetimesettingisfinished, itwillautomaticallyenter thevoicessetting (thescreenwilldisplay"SP") . Press" buttontoturnonorturnoffthesound, "ON" meansturnon thesound, "OFF" meansturnoffthesound,  pressbuttonstoconfirmtheselection.



2) Voicebroadcastcontent:

Attention, please!

Pleasekeepsilentandrelax.

Keepthecuffattheheartlevel.

① Ifyourbloodpressureisinnormalrange :

Thankyou.

Yourbloodpressureis:

Systolicpressurexxxmillimeterofmercurypillar.

Diastolicpressurexxmillimeterofmercurypillar.

Yourpulseisxxbeatsperminute.

Measuringresultisnormal.

Thank you.

Wish you a good health.

② If your blood pressure is not in normal range:

Measuring result is abnormal.

Your blood pressure is high/low.

Could not measure your pulse at this time.

③ Measuring error:

Error, (Mistake), please measure again

④ Other operation:




Average Blood Pressure

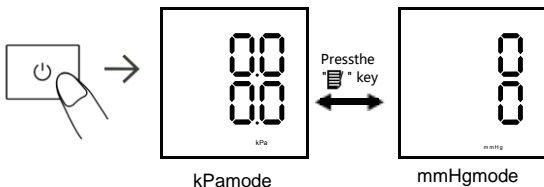
Last time your blood pressure was xxx, your pulse was xx

Low battery, please replace the battery

Low battery, please charge in time

(4) Unit display setting

In stand-by mode, keep pressing " " but  for about 10 seconds to enter the unit selection, and press " " to switch  mmHg/ kPa. Press " " to confirm the  tion; The default unit is mmHg.



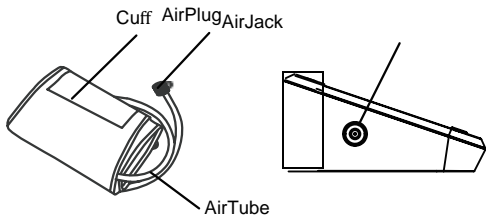
11. How to Take Proper Measurements

(1) Preparation before measurement

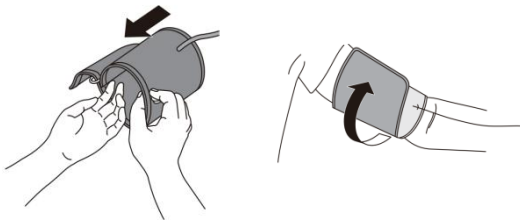
- Take off the clothes on the arm.
- Always measure in the same arm (generally the left arm).
- Remain still and keep quiet during measurement.
- Relax as much as possible and do not talk during measurement.
- Measure your blood pressure at about the same time every day.
- Do not measure right after physical exercise or a bath. Rest for 20 to 30 minutes before taking the measurement.
- Readings under the conditions listed below may affect results:
 Within an hour after dinner, after having wine, coffee, tea, sports; talking, being nervous, being in an unsteady mood, bending forward, moving, room temperature dramatically changing during measuring; inside a moving vehicle, repeated and continuous measuring.

(2) Applying the arm cuff

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

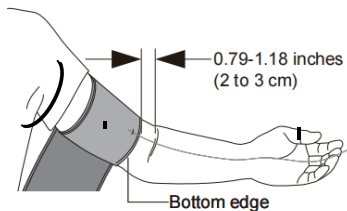


2) Place your hand through the cuff loop. Pull the cuff until it reaches your upper left arm.



Note

- The bottom edge of the arm cuff should be 0.8 - 1.2 inches (2 to 3 cm) above the inside elbow. The air tube is 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 cannot 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 arms 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.

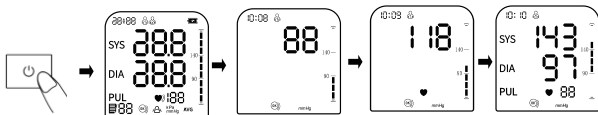


Warning: Do not kink the connecting tubing, as the resulting continuous cuff pressure can cause interference with blood flow and harmful injury to the patient.

(4) Taking measurement

Start measurement after wearing the cuff:

Press the "⏻" button. After all icons are turned on, the monitor will start inflating for measurement. Check the measured values after the measurement finished.



Note: If you feel uncomfortable during the measurement, press the "⏻" button immediately to stop measure.

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 heart beats 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.

(5) Memory function




1) Each measured value is stored automatically under the appropriate user group. This device can store up to 120 sets of measurements for each user. 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 measurement 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.

(6) Delete memory


In the power-off mode, press the "" button to select the user group whose measured values need to be deleted. Press the "" 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.

(7) Self check for cuff strap


The "" icon is always displayed on the screen when the cuff is worn correctly. When the cuff is worn too loosely, the "" icon will always flash to remind you. If the "" icon

is flashing all the time, please press the " " button to stop the measurement.

(8) “Keep Still” indication

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

(9) Turn off the unit

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

12. 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.
- **DONOT** use this monitor on an injured arm or an arm under medical treatment.

Cautions

- 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.

- **DONOT** use this monitor for infants, toddlers, children or persons who cannot express themselves.
- **DONOT** 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.
- **DONOT** use the device while you are on an intravenous drip or blood transfusion.
- **DONOT** 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.
- **DONOT** use this monitor for any purpose other than measuring blood pressure and pulse rate.
- **DONOT** disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.
- **DONOT** use in a location where there is moisture or a risk of water splashing this monitor. This may damage this monitor.
- **DONOT** use this monitor in a moving vehicle such as in a car.
- **DONOT** 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.

13.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 have 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, readjust 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 to some extent. For example, a person with the pulse of 70 beats 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 be 5mmHg-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 dissolved 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.

14. 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.
Er1	The pulse rate is not detected correctly.
Er 2	Too much disturbance (Move, talk, or magnetic disturbance during measurement).
Er3	The measurement result is abnormal.
Er 23	SYS value is lower than 57mmHg.
Er 24	SYS value is higher than 255mmHg.
Er 25	DI A value is lower than 25mmHg.
Er 26	DI A value is higher than 195mmHg.

*Troubleshooting

Anomaly	Inspection Items	Countermeasures
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 attempt to disassemble the device by yourself.		

15. 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:

- 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 1 min. 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.

16. Upkeep and Maintenance



water or neutral detergent



- Always keep the surface of monitor clean and tidy, helpful to prolong the service life of Blood Pressure Monitor.
- If the host 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 liquid to flow into the device.

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

17. Specifications

Mode	ARM-30A+
Measuring method	Oscillometric Measurement
Measuring part	Upper arm
Pneumatic pressure measuring range	0~295 mmHg
Overpressure protection	295 mmHg

mit			
Measuring range	Pressure value	SYS: 57~255 mmHg; DIA: 25~195 mmHg;	
	Pulserate	40~199 bpm	
Accuracy	Pressure value	±3 mmHg	
	Pulserate	±5%	
Low battery	<4.0V±0.1V: item will be turned off		
Autopower-off	1 minute withoutoperation		
Power source	4xAAA d.c. 6V or d.c. 5V, 1A type C cable		
Anti-electronic shock degree	Type BF		
Operation mode	Continuous operation		
Protection against harmful ingress of water or particular matter	IP21		
Weight	About 316g(without batteries)		
Dimension	108mm(length)*139mm(width)* 62mm(height)		
Screen size	81.4mm(length)* 82.9mm(width) 4.3 inches		
Cuff size	22~42 cm (8.6~16.5 inches)		
Monitor Service life	5 years		
Cuff Service life	10000 times		
Protection Against Electric Shock	Internally powered ME equipment (When using only batteries) Class II ME equipment (if equipped with AC adapter)		
	Temperature	5℃~40℃	If stored or used beyond

Operating environment	condition		ndthe
	Humidity condition	15%~90%RH	designated temperatureand
	Atmospheric condition	70kPa~106kPa	humidityrange, it willnotbeused properly
Transportationand StorageEnvironment	<p>Avoidstrong impact, direct impact, exposure or rainduringtransportation.</p> <p>Store your monitor and other components in a clean, safe location.</p> <p>Remove the arm cuff from the monitor.</p> <p>Gently fold the air tube into the arm cuff.</p> <p>ThepackagedBlood PressureMonitorshallbestoredindoors at the temperatureof -20℃ ~55℃ andtherelative humidityof 10%~93% ,atmospheric Condition: 70kPa~106kPa. without corrosive gas and with goodventilation.</p>		

Note: The specified power supply should meet the following condition:

Output voltage: DC 5V,

Output current:1000mA,

Comply with IEC 60601-1,

Class II

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

Comply with US and Canadian deviation requirements.

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: $\pm 5\%$

Bluetooth:

Arm blood pressure monitor using Bluetooth 4.2 technology, transmitting and receiving frequencies of 2402-2480MHz, modulation type GFSK, effective radiation power of 2.79dBm.

Statement: "The ARM-30A+ 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."

18. Appendix 1 EMC Information

Guidance and manufacturer's declaration - Electromagnetic emission		
<p>The Arm Blood Pressure Monitor is intended for use in the electromagnetic environments specified below. The customer or the user of the Arm Blood Pressure Monitor should assure that it is used in such an environment.</p>		
Emissions	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	<p>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.</p>
RF emissions CISPR 11	Class B	<p>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.</p>
Harmonic emissions IEC 61000-3-2	N.A.	
Voltage fluctuations/-flicker emissions IEC 61000-3-3	N.A.	

Guidance and manufacturer's declaration - Electromagnetic immunity

The Arm Blood Pressure Monitor is intended for use in the electromagnetic environments 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	30 A/m, 50/60 Hz	30 A/m, 50/60 Hz
Conducted RF IEC 61000-4-6	3 V signal input/output; 0,15 MHz-80 MHz 6 V in ISM and amateur radio bands between	3 V signal input/output; 0,15 MHz-80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 2 Hz

	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: The test 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 environments specified below. The customer or the user of the Arm Blood Pressure Monitor should assure that it is used in such an environment.

Radiated RF 0-4-3 (Test specifications for ENCLOSURE-PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Max. Power (W)	Distance (m)	IEC60601-1-2 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	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	745							
	780							
	810	800-960	GSM 800/900,	Pulse modulation	2	0.3	28	28
	870							

	930		TETRA 800, DEN 820, CDMA 850, LTE Band5	18 Hz				
	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 IEC 61000-4-39 (Test specific ations for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	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 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 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.



Shenzhen AOJ Medical Technology Co., Ltd.

Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing
Park, Xiaweyuan, Gushu Community, Xixiang Street, Bao'an District,
518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Email : info@aojmedical.com

Website : <https://www.aojmedical.com>

Tel : 86-755-2778 6026



ShareInfo GmbH

Heerdter Lohweg 83, 40549 Düsseldorf, Germany

Tel: 0049 179 5666 508

E-mail: EU-Rep@share-info.com

Made in China

FCC Statement

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.

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

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

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

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.