GIMA
PROFESSIONAL MEDICAL PRODUCTS

SFIGMOMANOMETRO
ARM BLOOD PRESSURE MONITOR
TENSIOMÈTRE À BRASSARD
MONITOR DE PRESIÓN ARTERIAL DE BRAZO
MONITOR DA TENSÃO ARTERIAL DE BRAÇO
OBERARM-BLUTDRUCKMESSGERÄT
ARMBLOEDDRUKMETER
ARMMONITOR FÖR BLODTRYCK
CIŚNIENIOMIERZ NARAMIENNY
KAR VÉRNYOMÁSMÉRŐ MONITOR
TENSIOMETRU ELECTRONIC DE BRAȚ
ΠΙΕΣΟΜΕΤΡΟ ΜΠΡΑΤΣΟΥ

Manuale d'uso
User Manual
Mode d'emploi
Manual de Usuario
Manual do Utilizador
Bedienungsanleitung
Gebruikershandleiding
Användarmanual
Instrukcja obsługi
Felhasználói kézikönyv
Manual de utilizare
Εγχειρίδιο Χρήσης

GIMA 49870

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MD

M49870-Rev.0-02-25

Table of Contents

Thank you for purchasing the Arm Blood Pressure Monitor. The device uses the oscillometric method of blood pressure measurement. It is intended for professional and domestic use in monitoring diastolic and systolic blood pressure and pulse rate.
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 manual.

2. Packing List

No.	Name	Quantity
1	Arm Blood Pressure Monitor with Cuff	1
2	User Manual	1
3	Quick Start Guide	1
4	Bluetooth Quick Start Guide	1
5	Type-C Charging Cable	1

3. Symbol Definition

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

	Caution: read instructions (warnings) carefully
	Type BF applied part
	WEEE disposal
	Follow instructions for use
	Keep in a cool, dry place
	Low voltage prompt
	Keep away from sunlight
	High
IP22	2 Protected against the entry of solid foreign bodies of dimensions equal to or greater than 12.5 mm; 2 Protected against the ingress of water drops when the device is tilted up to 15°
RoHS	RoHS mark
CE 0123	CE mark
	Manufacturer
	Date of manufacture
SN	Serial number
LOT	Lot number
EC REP	Authorized representative in the European Community
MD	Medical device
	Non-ionizing electromagnetic radiation
	Importer
UDI	Unique device identifier

4. Product Composition
This device 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.

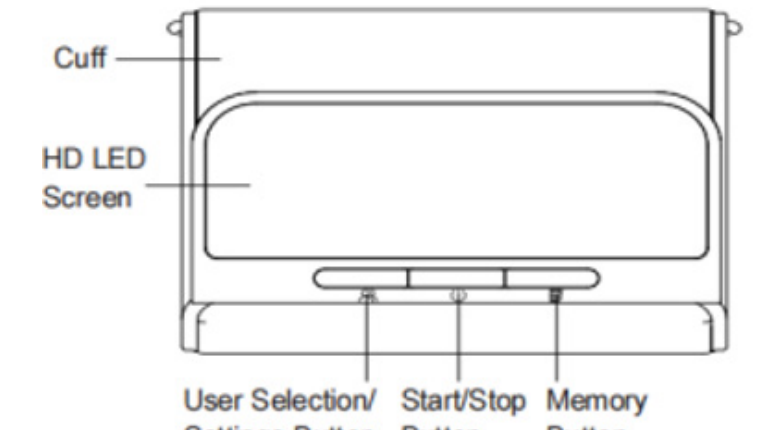
Intended users
1.Lay person or clinical professionals.
2.can read and understand the user manual.

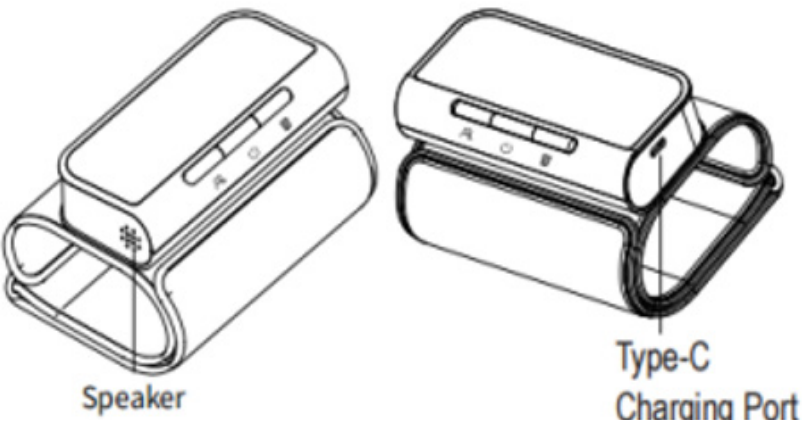
Clinical benefit
Patients can monitor systolic pressure, diastolic pressure and pulse rate at home at any time, greatly reducing the number of visits to the hospital, reducing the risk of travel and improving the quality of patient's life.

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.

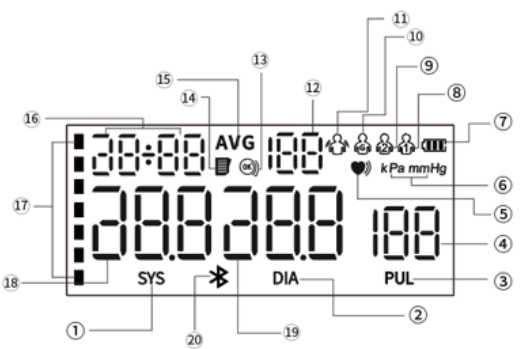
7. Product Parts

(1)Main Body





(2)Display Outline



① Systolic Blood Pressure Icon
② Diastolic Blood Pressure Icon
③ Pulse Rate Icon
④ Pulse Rate Value
⑤ "Irregular Heartbeat" Indicator
⑥ Blood Pressure Unit
⑦ Battery Indicator
⑧ "User 1" Icon
⑨ "User 2" Icon
⑩ "User (guest)" Icon
⑪ "Motion" Indicator
⑫ Memory Number
⑬ "Cuff Worn" Indicator
⑭ Memory Icon
⑮ "Average/Triple Measurement" Indicator
⑯ Date & Time
⑰ WHO Blood Pressure Indicator
⑱ Systolic Blood Pressure Value
⑲ Diastolic Blood Pressure Value
⑳ Bluetooth Icon

8. 3-color Backlit Indicator

Green Indicator Light for Normal

Yellow Indicator Light for Mild High Blood Pressure or Hypotension

Red Indicator Light for High Blood Pressure

Systolic Blood Pressure(mmHg)	Diastolic Blood Pressure(mmHg)	Color of Indicator	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 (or)

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

9. Preparation: Type-C Charging

Please check the device's power before using it. When the battery runs out, please use the manufacturer-provided Type-C charging cable (d.c. 5V, 1A) to charge the device till the "" indicator stops flashing.

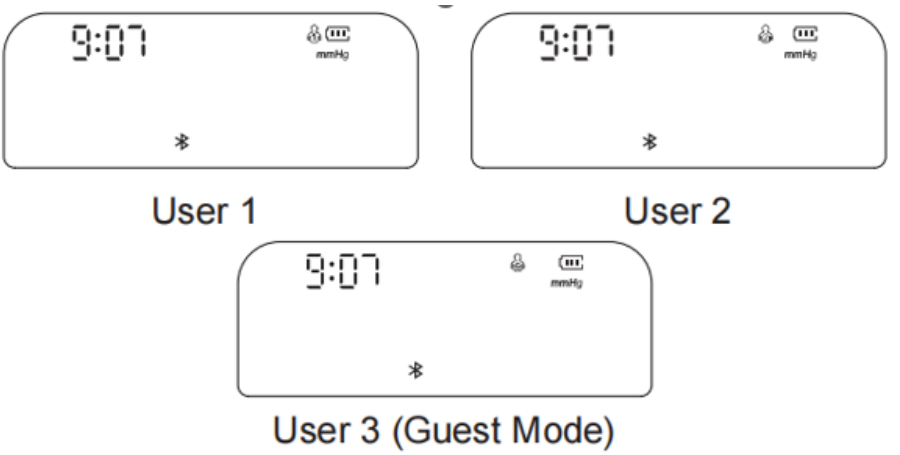
NOTE:

●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.

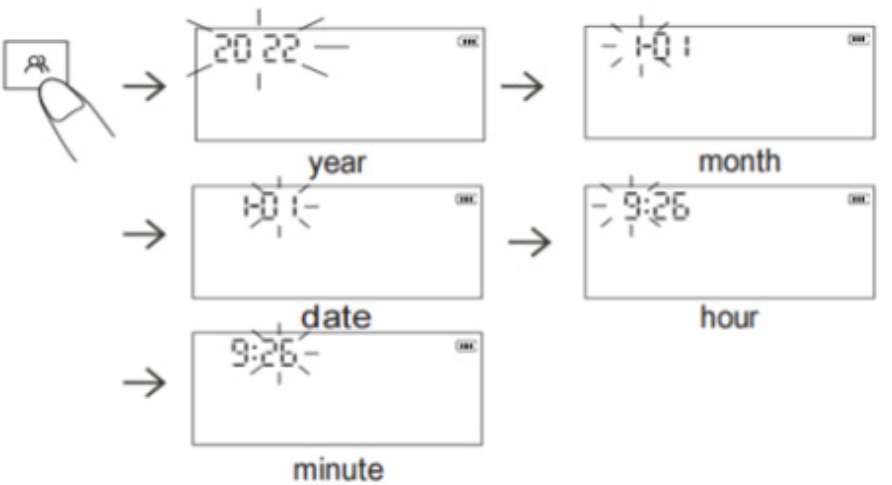
10. Function Setting

(1) To Select User

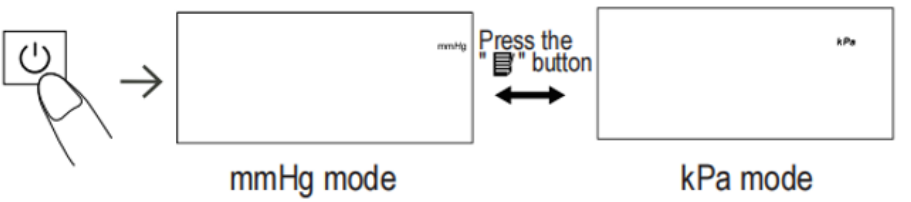
In power-off mode, press the "" button to enter the user group selection interface. Then press the "" button again to switch and select user groups.



(2) Year/Month/Date Setting
In power-off mode, press the “ “ button for about 3 seconds to enter the date setting, and “year” will flash. Press the “ “ button to adjust to the desired year, and then press the “ “ button to confirm the 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 step to set “date”, “hour”, and “minute”.



(3) Unit Display Setting
In power-off mode, keep pressing the “ “ button for about 3 seconds to enter the unit selection. Press the “ “ button to switch between mmHg and kPa, and then press the “ “ button to confirm the selection. The default unit is mmHg.



11. How to Take Proper Measurements

(1) Preparation before measurement

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 PROCEDURE.

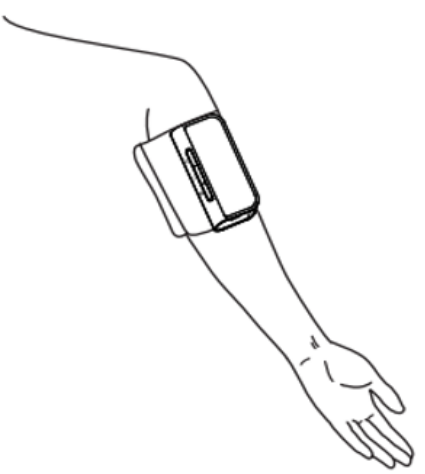
--Measure your blood pressure at about the same time every day.

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

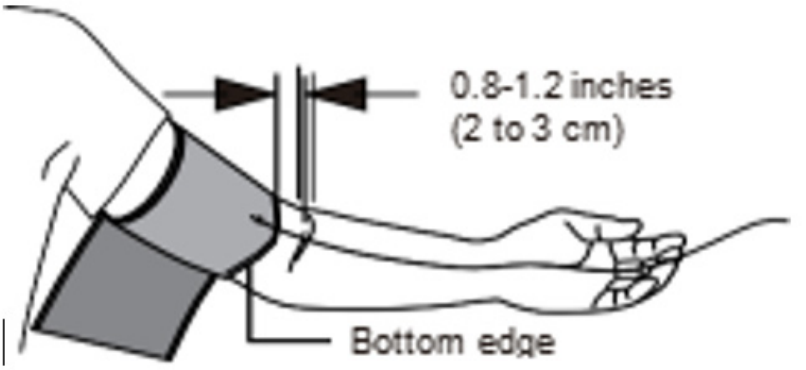
--Readings under the conditions listed below may affect results: Within an hour after dinner, after having wine, coffee, tea, sports; talking, being nervous, being in unsteady mood, bending forward, moving, room temperature dramatically changing during measuring; inside a moving vehicle, repeated and continuous measuring.

(2) Wearing the cuff correctly

1) Unroll the cuff. Place your arm inside it. (We strongly recommend to use your left arm.)

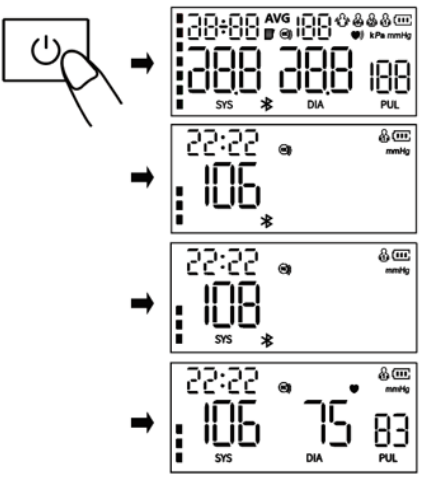


2) Make sure that the device's screen is positioned on your inner arm as illustrated in the diagram. The bottom edge of the cuff should be 0.8-1.2 inches (2 to 3 cm) above the inside elbow.



3) Tighten the cuff around your arm, so it can not move around your arm.
Note: Repeated measurement may result in blood congestion in the arm, which will affect the measurement result. Be careful not to rest your arm on the air tube.To avoid this situation, we advise that you can raise the left hand and hold the fist for several times, or take off the cuff and rest for at least 2-3 minutes before taking the measurement.
(3) Measurement tips
• 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 device should be placed on your inner arm at the same level as your heart, with the arm resting comfortably on a table.

(4) Taking a measurement
Press the " " button and the monitor will begin to inflate.
Please do not move or talk during the measurement.



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 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.

(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. (Note: There is no memory for "Guest".) Once the memory log is full, old values are refreshed with new ones.
2) In power-off mode, press the "M" button once and the device will display the average value of the blood pressure measurements of the last 2 or 3 times. Press the "M" button again, and the latest measured value will be displayed. Press the "M" button again and the rest memories will be displayed one by one.
(6) Delete memory
In the power-off mode, press the "U" button to select the user group whose measured values need to be deleted. Press the "M" to power off the device, then press the "M" once and then keep pressing the "M" button for 3 seconds to delete memories of the selected user and the " " icon will appear on the screen.
(7) "Cuff Worn" Detection
The "OK" 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 hand 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.
●DO NOT 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.

● 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. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
● 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.
●The maximum surface temperature of the product (near motor) is 41.6°C, do not use it continuously for a long time, otherwise it will cause measurement deviation and equipment heating, it is recommended that each measurement interval of

several minute.
●Do not operate when charging.

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.
● Also, 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 the patient might be using 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 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 finger tip 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 22~42cm (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
Er U	The inflation can not reach 30 mmHg in 12 seconds.
Er H	The inflation reaches 295mmHg,
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	Inspection Items	Countermeasures
Failure to power on	The battery is depleted	Recharge the device till the " " indicator stops flashing
Unable to measure due to display error	Whether the arm is moved when pressurization	Keep your arm and body still
	Whether you talk during measure-ment	Keep quiet while measuring the blood pressure
Air leakage of cuff	The airbag of the cuff is ripped	Please contact the dealer to replace with a new cuff. Don't change the cuff by yourself
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

15.1 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.

15.2 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.

15.3 Disposal

Dispose of your 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 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.

17. Specifications

Model	AOJ-33A
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	SIS: 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%	
Memory	It can be used for 3 users (user 1, user 2 and guest mode). 2 users*120 memories and guest mode without memory.	
Power Source	3.7V rechargeable lithium battery	
Charging Method	Type-C charging port; Charging voltage: d.c. 5V,1A	
Low Battery	When the power is lower than 3.4V, the device will be turned off.	
Dimension	123 mm (L) x 59 mm (l) x 28.2mm (H)	
Screen Size	75mm (L) x 35 mm (l) (3,2 inches)	
Cuff Size	22~42 cm (8,6~16,5 inches)	
Weight	About 225g	
Auto Power-off	1 Minute Without Operation	
Anti Electronic Shock Degree	Type BF	

Protection Against Harmful Ingress of Water or Particular Matter	IP22		
Service Life	5 years		
Protection Against Electric Shock	Internally powered supply		
Cuff Service life	10000 times		
Operating Environment	Temperature Condition	5 °C~40 °C	If stored or used beyond the designated temperature and humidity range, it will not be used properly.
	Humidity Condition	15%~90% umidità relativa	
	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. 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.
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
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%

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. 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 Bluetooth are measurement timestamp, measurement error code, systolic pressure, diastolic pressure, pulse rate, irregular pulse, and battery level.

18. Appendix 1 EMC Information

Guidance and manufacturer's declaration - Electromagnetic emission		
The Arm Blood Pressure Monitor is intended for use in the electromagn- etic environment specified below. The custo- mer or the user of the Arm Blood Pressure Monitor should assure that it is used in such an environ- ment.		
Emissions	**Complian ce**	**Electromagnetic environ- ment - 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 establishmen- ts, 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/flick er 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 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	±8kV contact ±2 kV,±4kV,±8 kV, ±15kV 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	SIP/SOP:1Kv	SIP/SOP:1Kv
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	SIP/SOP: 3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 2 Hz	SIP/SOP: 3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 2 Hz

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	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9	9
	745							
	780							
	810	800-960	GSM 800/900, TETRA 800, DEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28	28
	870							
	930							

	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

Statement: "The AOJ-33A 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 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.

EU Declaration of Conformity

We, the undersigned (☑ Manufacturer, or ☐ The manufacturers authorized representative)

Manufacturer : Shenzhen AOJ Medical Technology Co., Ltd.

Address : 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

Certify and declare under our responsibility that the following product:

Product name : Arm Blood Pressure Monitor

Model No. : AOJ-33A

Brand name : -

Hardware version : V1.0

Software version : V1.0.0

Conformity with the relevant Union harmonisation legislation:

☑ Radio Equipment Directive (2014/53/EU)

Conformity with the following relevant harmonised standards, which are in force within the EEA:

Essential requirement		Applied standard	Refer to report
Article 3.1(a)	Health	EN 62479:2010 EN 50663:2017	CHTEW22120120
	Safety	EN 62368-1:2014+A11:2017	CHTSE22120129
Article 3.1(b)	EMC	ETSI EN 301 489-1 V2.2.3: 2019-11 ETSI EN 301 489-17 V3.2.4: 2020-09	CHTEW22120119
Article 3.2	Radio	ETSI EN 300 328 V2.2.2: 2019-07	CHTEW22120118

Where applicable, all essential radio test suites have been carried out

Type	Model No.	Manufacturer
AC Adapter	-	-
Battery	602040	Dongguan Zhongchengsheng Technology CO., LTD.

Notified body involved

None

Additional information

None

Signed for and on behalf of manufacturer

CE

Name : Jack Wang

Title : VP

Email : sales@aojmedical.com

Signature : Jack Wang

Date : 05/02/2025