REV.00
Doc. No.: GAD-A02OIM-01

User Manual
Upper Arm Electronic Blood Pressure Monitor

Model: A02-SE4

Thank you for selecting our Upper Arm Electronic Blood Pressure Monitor. Please read the user manual carefully and thoroughly so as to ensure the safe usage of this product. Keep this manual for further reference in case any issues arise.

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Table of Content

1. Introduction

This digital blood pressure monitor uses the oscillation method to measure blood pressure. This means that the monitor can detect the movement of your blood in the brachial artery and convert your blood pressure into a digital reading. This monitor automatically detects blood pressure without stethoscope and is easy to use.
Each measurement result will be displayed on the screen and automatically stored. A total of 2x90 sets of memory. This unit has a blood classification index and it could be used to easily check your classification index.

Measurement Principle:
This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the atmospheric pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsation , which is used to determine the systolic and diastolic pressure, and also pulse rate.

2. Symbol description

Warning/precautions symbols

The warning signs and graphic symbols in the manual are intended to enable you to use the product safely and correctly and to prevent harm to you and others.Warning marks and graphic symbols are described as follows:

 Warning	A warning alerts the reader about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.
 Precautions	Indicating a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.
Contraindications	Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit. There may be persons in whom the device should not be used because of their health status.
Notes	Indicates the need for attention, if not attention may lead to incorrect use of the product or property device damage.

Other Symbol description

	Applied part of type BF		Type of protection against electric shock: Class II
	Refer to instruction manual		Manufacturer

	Disposal in accordance with Directive 2002/96/EC （WEEE）		Fragile, handle with care
	Complies with FCC rules		Keep dry
	Serial number		Date of manufacture
	This device has not been tested for use in an MR environment and should not be used exposed to MR environments while patients are wearing the device. Keep it outside the MRI scanner room.		
IP21	The first number 2: Protected against solid foreign objects of 12.5 mm Φ and greater. The second number: Protected against vertically falling water drops when vertically dripping. Vertically falling drops shall have no harmful effects when the enclosure is titled at vertically dripping, on either side of the vertical.		

3. Indications for Use/intended use:

Indications for Use:

Measure blood pressure (systolic and diastolic) and pulse rate.

Intended use:

Upper Arm Electronic Blood Pressure Monitor is intended for used by a person older than twelve (12) years to measure the systolic and diastolic blood pressure and pulse rate.

[Use environment] home or hospital

[Patient Population] Person older than 12 years

4. Safety information

Contraindications

- The device is not suitable for use on the women who are or may be pregnant.
- The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defifibrillators.

Warning

- DO NOT adjust medication based on measurement values from this Upper Arm Electronic Blood Pressure Monitor. Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat High Blood Pressure.
- Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pregnancy, pre-eclampsia, renal diseases. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement

reading.

- Do not use the device on the injured arm or the arm under medical treatment.
- Do not apply the cuff on the arm while on an intravenous drip or blood transfusion.
- Do not use the device with other medical electrical (ME) equipment simultaneously.
- Do not use the device in the area of high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanner. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT use this monitor in oxygen rich environments or near flammable gas.
- Please ask your doctor about your normal blood pressure for right direction before take you take the measurement by yourself.
- This product applies only for person older than twelve (12) years. Please keep the unit out of reach of of infants, toddlers or child.
- Don't serviced or maintained while in use .
- Don't scratch, damage, process, excessively bend, pull or twist the USB cable, damage to the USB cable could cause fire or electric shock.
- Don't plug or unplug the AC adapter with wet hands.
- Only the original accessories (include the cuff and battery) or the recommended accessories (power adapter) that described in this user manual can be used, use other accessories will cause the device damage or inaccurate reading.

Precautions

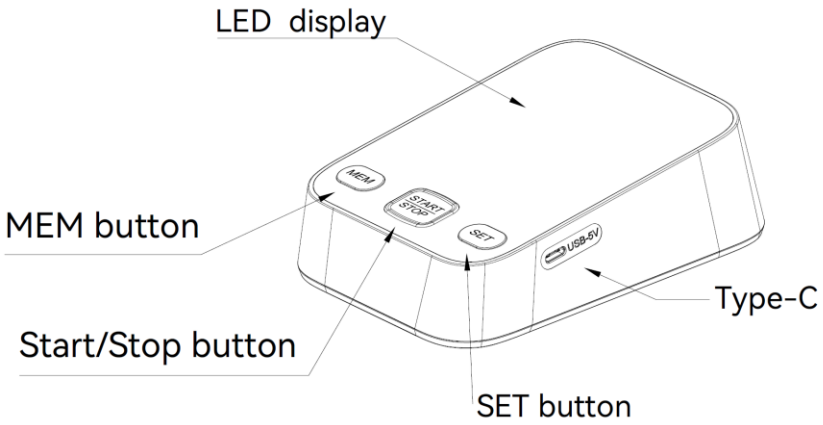
- If the cuff causing any discomfort, please turn off the equipment by press the START/STOP BUTTON and consult with your physician.
- Do not forcibly crease the cuff excessively, continuous cuff pressure may lead to blood flow interference and result in harmful injury to the patient.
- DO NOT take measurements more often than necessary because bruising, due to blood flow interference, may occur.
- Do not apply of the cuff over a wound, as this can cause further injury.
- Consult with your physician before using this monitor on a arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury.
- Consult with your physician before using this monitor if you have had a mastectomy or lymph node clearance.
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.The pressurization of cuff can temporarily cause loss of function of simultaneously used monitoring medical electrical (ME) EQUIPMENT on the same limb.
- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.

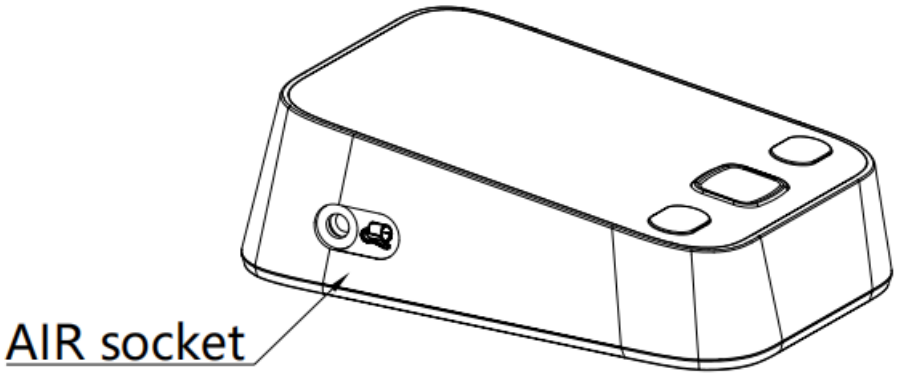
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- DO NOT use this monitor for any purpose other than measuring blood pressure.
- DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This may damage this monitor.
- Don’t store or use the monitor and cuff under the sunshine, high or low temperature and humidity (section ”specification”), or someplace which maybe get in touch with fire or water. Otherwise, it may cause inaccurate reading.
- DO NOT use this monitor in a moving vehicle such as in a car.
- This monitor is calibrated at the time of manufacturing, if the monitor is used according to the instruction, periodic recalibration is not required. If it is inaccuracy often, please contact your retailer or customer Services.
- Do not disassemble, repair, or remodel the main unit or the cuff of the Upper Arm Electronic Blood Pressure Monitor by yourself. If necessary, contact your retailer or customer Services.
- Do not drop the monitor or subject device to strong shocks or vibrations.
- ONLY use this monitor on persons whose arm circumference is within the specified range of the cuff.
- Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

Remark：
During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5 and ISO 10993-10/-23. It will not cause any potential sensitization or irritation reaction.

5. Product description

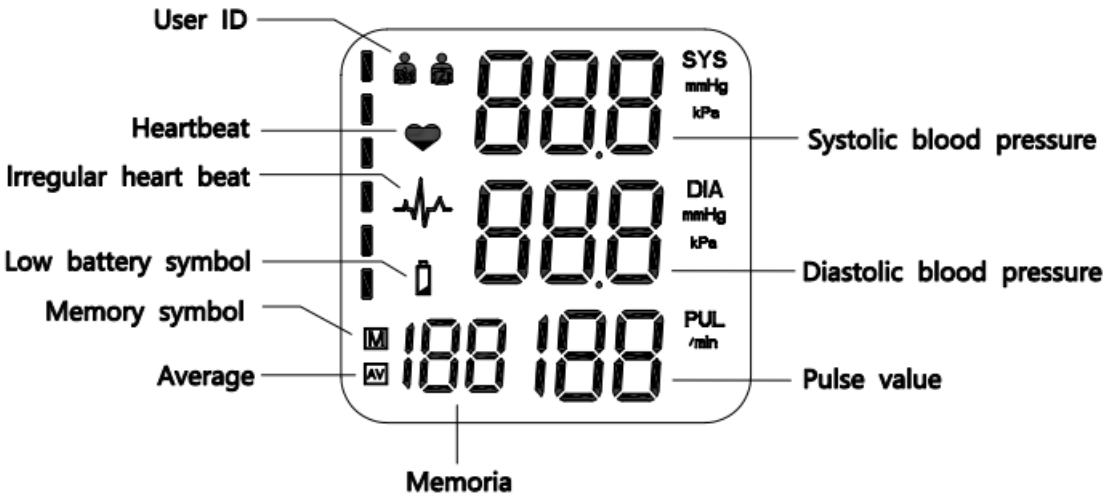
5.1 main unit





Name	Description
SET button (Setting button)	Press the Setting button when powered off to enter the setting mode; In setting mode, press this button to confirm the setting value; Assist in clearing memory.
Start/stop button	Turn on/off the device. Assist in clearing memory.
MEM button Memory button	In setting mode, press this button to adjust the setting value; In the memory query mode, press this button can check the memory.
LED display	Displaying information of measurement, battery power etc.
Type-C hole	Connecting to the output end of USB cable.
SIM card slot	The position of the SIM card(The function of SIM card is to realize wireless data transmission).
Air socket	Connect to the air hose.

5.2 LED display



Description	Explanation
User ID	appears when the monitor is operated by User 1. appears when the monitor is operated by User 2.
Blood pressure classification	Indicates the blood pressure level
Memory symbol & Memory times	Indicate it is in the memory mode and which group of the memory is.
Irregular heart beat	Irregular heartbeat detected during measurement.
Low battery symbol	Indicate the battery power is low.
Heartbeat	Heartbeat detection during measurement.
Pulse value	Measurement data of Pulse
Diastolic blood pressure(DIA)	The low pressure measured.
Systolic blood pressure(SYS)	The high pressure measured.
Average	Average value for 3 memories

5.3 Package list

Parts		Quantity	Part no.:
Upper Arm Electronic Blood Pressure Monitor		1PCS	A02-SE4
Battery (installed in main unit)		4PCS	AA
Cuff (with air hose)	22cm~42cm	1PCS	2242
User Manual		1PCS	/

6. Operating Instructions

6.1 Charging Battery

After powering on, if the low battery symbol is displayed on the LED, it means the battery is low and the device is unable to measure, please replace batteries in time, otherwise, it will automatically shutdown after 3 minutes.

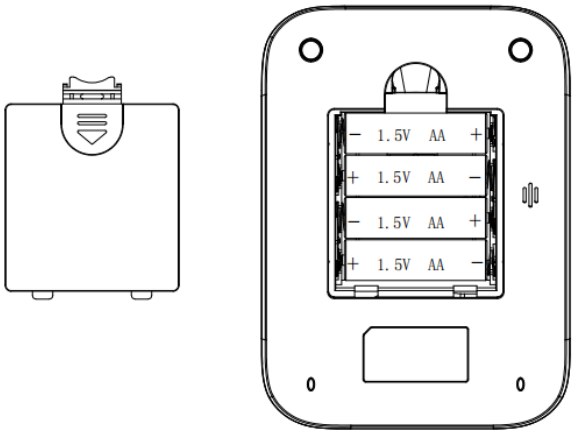
Notes:

- The four batteries supplied with the product can ensure the power consumption for at least 300 times measurements.
- When the product is not used for a long time, the battery will discharge slowly. Please replace the battery when using it again.

6.2 Installing and Replacing the Battery

After fully charging the battery, if the working time of battery is shorter than before and you want to replace, you can contact your dealer or manufacturer for a new battery, use other battery may lead to failure installation or device damage. see the last page for the manufacturer's contact information. Install the battery as follows:

1). Remove the battery cover from the battery compartment, following the arrow for proper removal.
2). Insert or replace 4pc 1.5V AA alkaline battery and ensure the battery is in the proper direction. Make sure the “+” (positive) and “-”(negative) polarities of batteries match the polarities marked on the battery compartment.
3). Close the battery cover



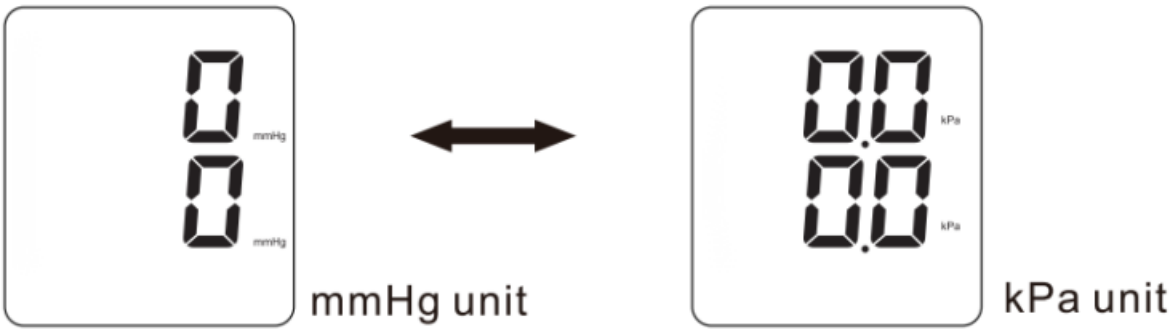
Note:

- To replace batteries, turn your monitor off and remove old battery. Then replace with a new alkaline battery at the same time.
- ONLY use 1.5V AA alkaline battery offered by dealer or manufacturer with this monitor. DO NOT use other types of battery.
- DO NOT insert battery with their polarities incorrectly aligned.
- If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult with your physician immediately;
- If battery fluid should get on your skin, wash your skin immediately with plenty of clean, lukewarm water. If irritation, injury or pain persists, consult with your physician.
- Periodically check battery to ensure they are in good working condition, stop use and replace the new battery when you find the battery was bulging or leaks.
- Do not put the battery into fire, disposal of used battery should be carried out in accordance with local regulations.

6.3 System setting

1) Setting unit

Press the Setting button when powered off. The unit will display on LED, the default unit is mmHg. Press the memory button to switch between mmHg and kPa. When you find the unit you want, press the setting button to confirm, then the device will enter the Speaking setting mode.



Remark: Reinstalling the battery will cause the unit to return to the default state(i.e. mmHg).

2)Setting User

In the User setting mode, the screen will display or (default is). Press the MEM button to switch between the options, and press the SET button to confirm your selection.

Remark: Reinstalling the battery will cause the unit to return to the default state.

6.4 Proper Use of the Unit

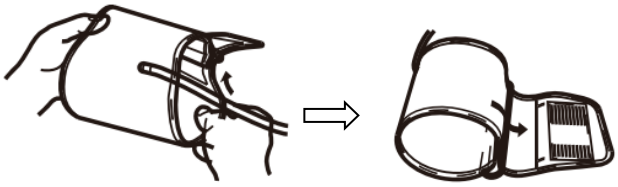
6.4.1 Pre-measurement

1) Check the device before use:
   - Check the monitor to ensure that the main unit and cuff are free from damage and cracks.
   - Check whether the battery is leakage, If there is leakage, please replace the battery.
   - Check whether the display is normal and without E-X(X stands for Arabic numerals) prompt.
   - Check whether the battery has enough power. If the battery is low, please change the battery in time.
2) In order to avoid affecting the accuracy of the monitor, avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.
3) Please sit quietly for at least 5 minutes before taking the blood pressure measurement.
4) A single measurement does not provide an accurate indication of your true blood pressure. we recommend you to repeat the measurement at least two times for accuracy. Wait at least 1 minutes between measurements, this allows your blood circulation to recover.
5) Stress raises blood pressure. Avoid taking measurements during stressful times.
6) Try to measure your blood pressure regularly at the same time every day, because blood pressure changes with time.
7) For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.
8) Factors affecting blood pressure measurement
   a. If the user supports the arm hard, it may raise the blood pressure reading.

b. if the cuff around the arm is lower than the horizontal height of the heart, the blood pressure will be higher.
c. Too loose or too tight cuffs can cause false readings.
d. In different postures, different environments and different physical conditions, the measured blood pressure values will be different.

6.4.2 Fitting the Cuff

1)Place the cuff flat on the table with the velcro side facing down. Pass the end of the cuff through the metal loop so that a circle is formed, velcro closer is now facing outward (ignore this step if the cuff has already been prepared).



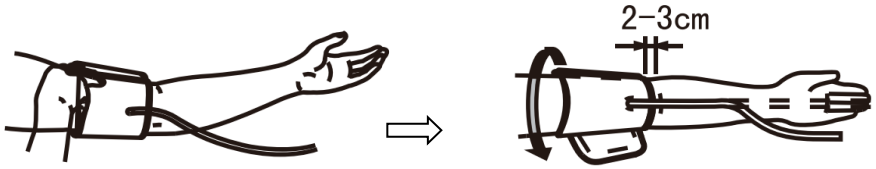
2)Firmly insert the air hose connector of cuff to the air socket of main unit.

3) Remove all jewelry, such as watches and bracelets from your left arm.

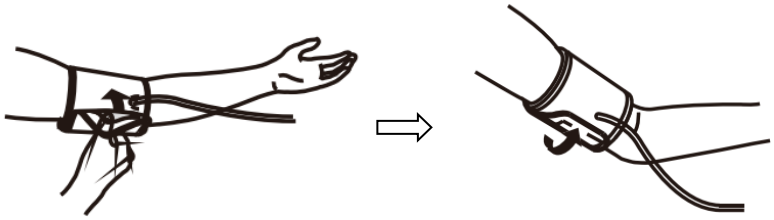
Note: if it is not possible to fit the cuff to your left arm, it can also be placed on the right. However, all measurements should be made using the same arm.

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

4) Hold your arm with your palm facing up, wrap the cuff over the upper arm, then position of tube off-center toward the inner side of arm in line with the ring finger. Make certain that the lower edge of the cuff lies approximately 2 to 3 cm above the elbow and the air hose leaves the cuff on the inner side of the arm.



5)Tighten the cuff and close the cuff by affixing the velcro. The cuff should not be rolled too tightly or too loose. The tightness that can put two finger in is the most appropriate.



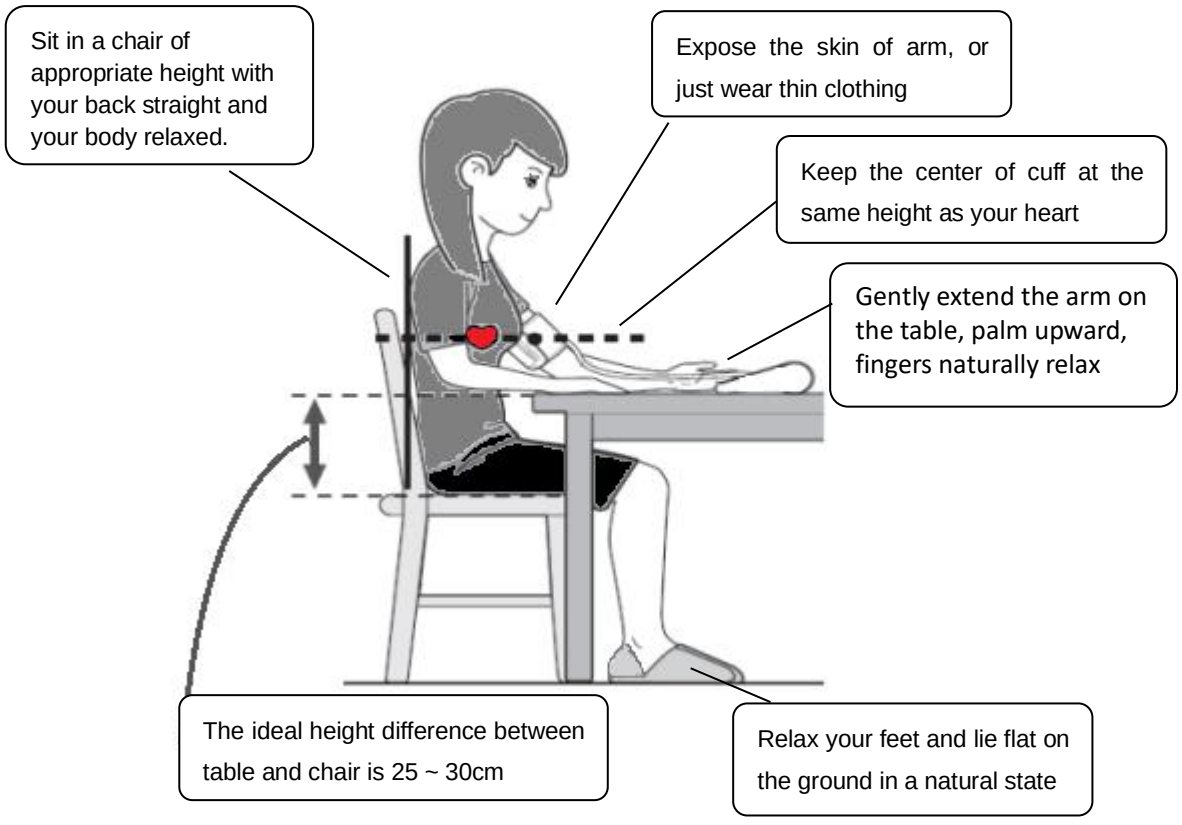
6)Lay your arm on a table (palm upwards) so that the cuff is at the same height as the heart. Do not bend the air hose.

6.4.3 Sitting Correctly

a. Please sit comfortably and sit upright in a chair;

b. The cuff should maintain at the same level as the heart. Place your elbow on a table so that the cuff is at the same level as your heart. Relax your arm and hand. Make your measurement arm resting on a flat surface. Turn your palm upwards. Do not clench your fist, or bend your arm forward. Do not cross your legs and keep your feet flat on the ground.

c. Take 5~6 deep breaths before starting measurement.



6.4.4 Start the Measurement

After the cuff has been appropriately positioned on the arm, the measurement can begin as follows:

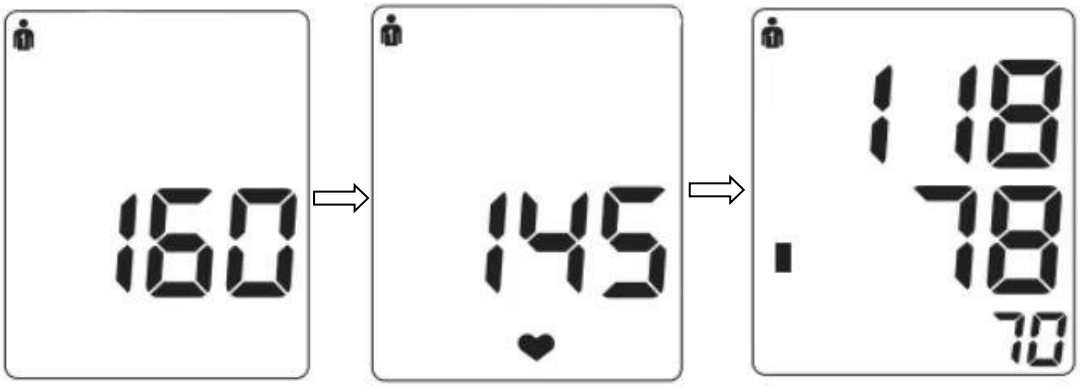
1) Press the START/STOP button. All symbols will appear on the display for 1s, the full display of LED is the same as chapter “5.2 LED display”. Remain still and do not move or talk until the entire

measurement process is completed. The monitor will automatically measure your blood pressure according to the following procedure:

Step1: After full display, the monitor start to inflate the cuff, The rising pressure in the cuff will show on the display;

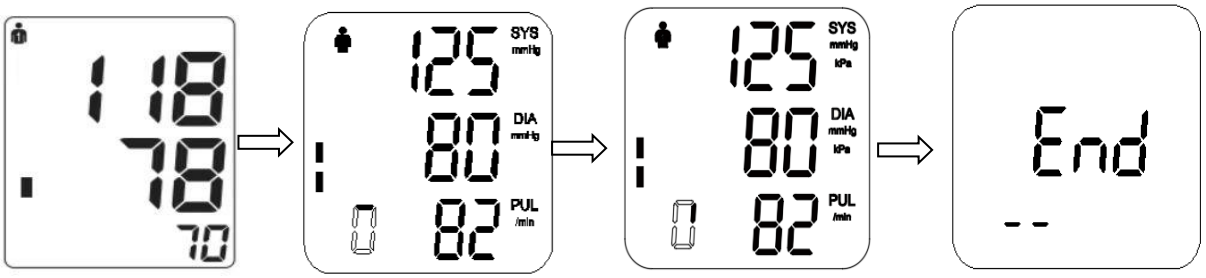
Step 2: After the proper pressure has been reached, the pump will stop, and the pressure will gradually fall. If the inflation is insufficient to take a reading, the device will automatically re-inflate to a higher pressure. When the device detects the signal, the heart symbol ❤ on the display starts to flash.

Step 3: When the measurement has been completed, the systolic, diastolic and pulse rate will appear on the display.



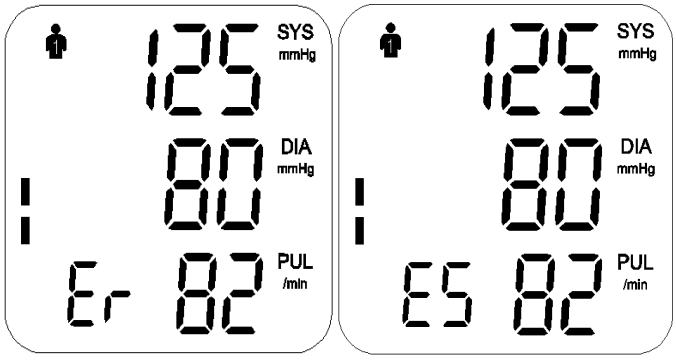
Remark:

- *If Irregular heartbeat is detected during the measurement, the symbol "〰" will appear along with the measurement result.*
- *Once the measurement is finished, the device will automatically upload the data to the specified website. A rotating signal bar will show in the lower left corner of the LED. LED shows "nd" after a successful upload and the device automatically shuts down after 5 seconds.*



the "H" means the strong transmission signal, if the "L" is display, it means the transmission signal is weak. These indicators will appear once a measurement is complete and the data upload begins.

- If "Err" is displayed on the lower left corner of the LED,it means the upload failed, the reason may be that the SIM card owe fee or the network environment is poor. Upload failure notification Er5 indicates no SIM card was detected or the SIM card is damaged. After troubleshooting, the data that failed to upload will continue to be uploaded automatically.



2) Press “START/STOP” button to turn off, otherwise the monitor will power off automatically after 5s of no operation.

Discontinuing a Measurement：

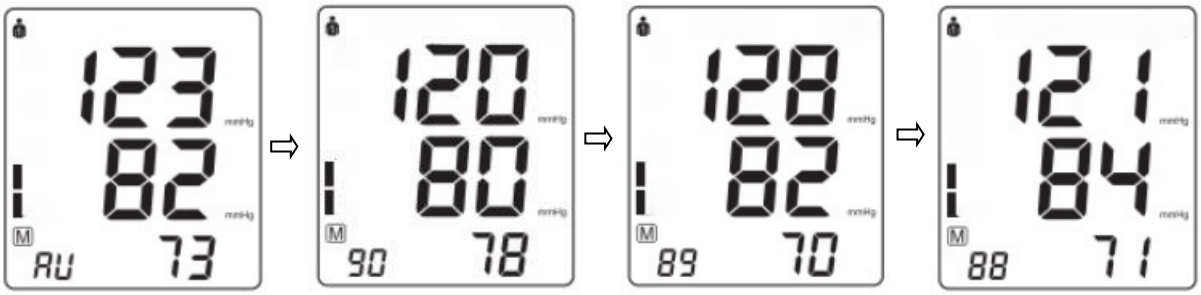
If it is necessary to interrupt a blood pressure measurement for any reason (e.g., the patient feels unwell), the START/STOP button can be pressed at any time. The device will immediately decrease the pressure in the cuff.

6.4.5 Memory-recall of Measurements

The blood pressure monitor automatically stores 2x90 sets of measurement values. The oldest record will be replaced by the latest measurement value when there are more than 90 sets of memories for each user.

1) Read Memory Record

At the power off state, press the MEM button to query the memory of current user. The average of the latest 3 measurements will display. Press the MEM button again it will show the latest measurement taken, press the MEM button step by step to view the measured values of each time in sequence.



Average value of latest measurement **the latest record 1** **the latest record 2** **the latest record 3**

- If there are two groups only, it will display the average of the latest 2 measurements, if there is one group, the latest measured value is directly displayed;
- If no measurement before, the LED will display user ID, memory icon and “no” .

2)Clear memory

Delete all stored memories:

Under the powered off status, press the SET button until “CL” appears.

Press the START/STOP button. “CL” will flash to clear all memories.

If you press the MEM button after this, the screen will display memory symbol and "no" indicating no memory is stored on the device.

Remark:

- Take the battery out won’t lead to a record missing.
- You cannot delete a group of memory separately, you can only delete them all at once.
- When the memory capacity is full, the old measured data will be covered by new data.

6.4.6 Speaking function

During usage, if you turn on the speaking function, the monitor will broadcast the following content：

Voice broadcast

Triggers for making the voice broadcast	Content of Voice broadcast
Power on	Place the cuff at the same level as your heart, don`t move and keep quiet
After completing measurement	Your systolic pressure is XX mmHg(or kPa); The diastolic pressure is XX mmHg(or kPa); The pulse rate is XX Beats Per Minute.
Broadcast the average memory when entering the memory mode	Your average for the last Y measurements: Your systolic pressure is XX mmHg(or kPa); The diastolic pressure is XX mmHg(or kPa); The pulse rate is XX Beats Per Minute.
Broadcast the single memory under memory interface	Your systolic pressure is XX mmHg(or kPa); The diastolic pressure is XX mmHg(or kPa); The pulse rate is XX Beats Per Minute.
When the LED display low battery symbol	Battery is Low
Broadcast when LED display Err symbol.	Error, please measure again

Note:

- XX is the voice content corresponding to the measured actual value.
- Y means 1,2,3.

6.4.7 Blood pressure classification function:

The monitor has the function of blood pressure classification prompt, which can indicate the corresponding blood pressure range through the blood pressure prompt bar:

Display of Prompt bar	Systolic blood pressure (SYS)	Diastolic blood pressure (DIA)
	<120mmHg (16.0kPa)	<80mmHg(10.7kPa)
	120mmHg(16.0kPa)-129mmHg(17.2kPa)	80mmHg(10.7kPa)-84mmHg(11.2kPa)
	130mmHg(17.3kPa)-139mmHg(18.5kPa)	85mmHg(11.3kPa)-89mmHg(11.9kPa)

	140mmHg(18.7kPa)-159mmHg(21.2kPa)	90mmHg(12.0kPa)-99mmHg(13.2kPa)
	160mmHg(21.3kPa)-179mmHg(23.9kPa)	100mmHg(13.3kPa)-109mmHg(14.5kPa)
	≥180mmHg(24.0kPa)	≥110mmHg(14.7kPa)

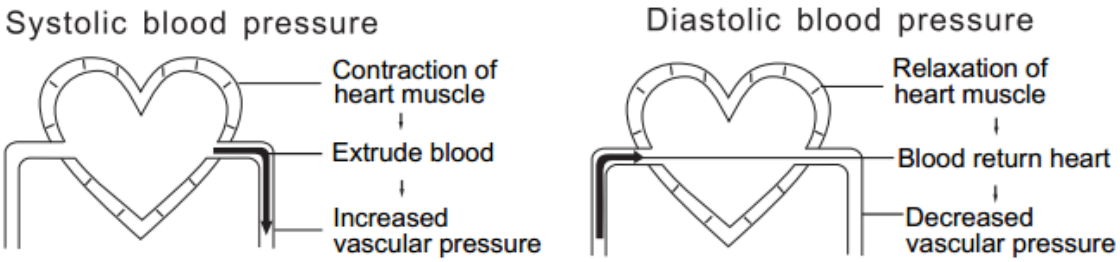
6.5 Wireless data transmission function（A02-SE4）

The device had a built-in SIM card, with this SIM card, after completing blood pressure measurement, you do not need to do any other operations, the measurement results will be automatically uploaded to a network platform. In this way, you can let your physician know the measurement history on the specified network platform. For how to view the history of measurement data on the network platform, please refer to user manual of " Wireless data query".

7. About Blood pressure

7.1 What are systolic pressure and diastolic pressure?

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



7.2 What is the standard blood pressure classification?

Blood pressure classification according to 2017 Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure, there is four levels for blood pressure classification and two hypertensive crises: emergencies and urgency as following:

BP classification		Systolic	Diastolic
BP classification	Normal blood pressure	＜120mmHg	And ＜80mmHg
	Elevated blood pressure	120mmHg ~ 129mmHg	And ＜80mmHg
	Hypertension: Stage 1	130mmHg~139mmHg	Or 80mmHg~89mmHg
	Hypertension: Stage 2	≥140mmHg	Or ≥90mmHg
hypertensive	Hypertensive urgency	＞180mmHg	Or ＞120mmHg

crises	Hypertensive emergency	＞180mmHgtarget organ damage	Or ＞120mmHg target organ damage

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

Source: ACC/AHA 2017 High Blood Pressure Clinical Practice Guideline.

Warning

- Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

7.3 Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, the monitor records all the pulse intervals and calculate the average; if there are two or more pulse intervals, the difference between each interval and the average is more than the average value of ±25%, or there are four or more pulse intervals, the difference between each interval and the average is more than the average value of ±15%, the irregular heartbeat symbol appears on the display when the measurement results are appeared.

Warning

- The appearance of the icon indicates that a pulse irregularity consistent with an irregular heart-beat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

8. Care and Maintenance

8.1 Cleaning and disinfection

The device is a kind of multi-patient use device. The device should be cleaned and disinfected in between uses, as necessary. The cuff (include the air hose) and main unit should be thoroughly cleaned, and the cuff (applied part) shall be disinfected. Wait 10 minutes after cleaning/disinfection before use.

Before performing cleaning and disinfection procedure, wash your hands with hand sanitizer first.

Cleaning/disinfecting the accessories at room temperature 5℃~ 40℃ as below:

➢ **Cleaning method:**

1) Clean the device with a soft cloth dampened with the soapy water. Until no visible contaminants remain.
2) Wipe off the cleaning solution on the device with a soft cloth dampened with tap water until no visible cleaning agent remains.
3) Air dry the device thoroughly after cleaning.

- **Disinfection method:**

Cleaning the cuff as above method before disinfection.

1) Disinfect the cuff with a soft cloth dampened with the 70% isopropanol for 3 minutes.
2) Dry the cuff by placing the cuff at room temperature for 10min to evaporate the residual disinfection solution.

Note：

- Don’t use gasoline, diluent and other irritating liquid to wipe the device in case it causes malfunction or the components are damaged or discolored.
- Do not hold the device under running water, do not submerge it in water or other liquids.
- Ensure that no liquid penetrates into the device. If this happens, please use it again after the device is completely dry.
- Be sure that the device is turned off and the AC adapter is disconnected from the AC socket when cleaning/disinfecting the device.

8.2 Maintenance

1) We do not authorized any institutions or individuals to maintain and repair of the product. If you suspect that the products have any questions, please contact the manufacturer or distributor to handle the case.
2) The user must not attempt any repairs to the device or any of its accessories. This may cause an inaccurate reading. Please contact the retailer for repair.
3) Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

Remark:

- Do not to twist the cuff.
- Do not press the Start/stop button before wear the cuff in a right way.
- Do not apart or refit the monitor and cuff.
- Do not drop the monitor, avoid intense shaking and collisions.
- If you are not going to use this monitor for a long period of time (more than 3 months), please take out the battery from the monitor.

8.3 Calibration

The Upper Arm Electronic Blood Pressure Monitor is initially calibrated at the time of manufacturing. If this monitor is used according to the use instruction, periodic re-calibration is not required. If any time your doubt the accuracy of measurement, please contact distributor or manufacturer.
The service life (i.e.working life) of the monitor is 5 years. Once the service life of monitor was exceeds 5 years, please change a new Upper Arm Electronic Blood Pressure Monitor.

8.4 storage

Keep your monitor in the gift box when not in use.
• Store your monitor in a clean, safe location.
Do not store your monitor:
• If your monitor is wet.

• In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach. Please store the products according to the requirements of "storage condition" in section "Specifications" of this user manual.
• In locations exposed to vibrations or shocks.

9. Exceptional Situations

Error Indicators

The following symbols will appear on the display when there is an abnormal.

Symbol	Cause	Correction
E-1	Weak signal or sudden pressure change	1)Wrap the cuff properly. 2)Remeasure.
E-2	Strong external disturbance	1)keep away from high radiant device. 2)Keep quiet. No chatting while taking measurement
E-3	Error during inflation	1) Wrap the cuff properly 2) Make sure the air connector is properly inserted into the unit. 3) Remeasure.
E-5	Abnormal blood pressure	Repeat measurement after relaxing for 30 minutes. If unusual readings occur 3 times, contact your doctor.
Err	SIM card owe fee or the network environment is poor.	Contact your dealer to recharge fee, or measure again in a good signal environment
Er5	no SIM card was detected or the SIM card is damaged	Contact the dealer.
	Low battery	Replace 4 new AA batteries.

Troubleshooting Solutions

Problem	Check	Solution
No power	Is battery powered?	Change the battery
No inflation	Is plug (air hose connector) inserted?	Reinsert plug securely.
	Is plug broken / leaking?	Replace with new cuff
Cuff leak	Is the cuff loose?	Wrap the cuff tightly.
	Is the cuff broken?	Replace with new cuff.

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

10. SPECIFICATIONS

Measurement method	Oscillometric method
Measurement site	Upper Arm
Pressure display range:	0mmHg (0.0kPa) ~ 299mmHg(39.9kPa)
Measurement range:	Pressure Measurement range:

	SYS: 50mmHg(6.7kPa) ~ 255mmHg(34.0kPa) DIA: 30mmHg(4.0kPa) ~ 200mmHg(26.7kPa) Pulse measurement range: (40-199) beat/minute
Accuracy:	Pressure: ±3mmHg (0.4kPa) Pulse value: ±5% of reading
Measuring resolution:	1 mmHg/0.1kPa
Memories recall	Automatically stores the last 90 measurements for each user (a total of 180 for two users)
Display	LED digital display
Dimensions of main unit	Approx.L145 mm×W106mm×H47mm
Weight	Approx.259 g (Excluding the battery and cuff)
Power supply	4pcs AA battery /USB 5V 600mA
Measurable arm circumference	22 cm to 42 cm
Operating conditions	Temperature range: +5℃ to +40℃, Relative humidity range: 15% to 93%RH, Atmospheric pressure range: 86kPa to 106kPa
Storage & transportation conditions	Temperature: -20℃ to +55℃, Relative humidity range: 10% to 93%RH, Atmospheric pressure range: 86kPa to 106 kPa
Protection against electric shock	Internally powered ME equipment
Service life (i.e. working life)	5 years
Shelf life	No shelf life requirement
Ingress of waterproof	IP21
Applied part	Type BF (arm cuff)
Software version	GA1.0
No Sterilize requirement	
Not category AP / APG equipment	
Mode of operation: continuous operation	

11. Summary of clinical testing and baseline demographic

This monitor is clinically investigated according to the requirements of ISO 81060-2:2018. In the clinical validation study, the cuff were tested for clinical accuracy with the main unit, 90 subjects were used for determination of blood pressure for each cuff.

The age range of subjects was over 12 years old;

Among the 90 subjects, at least 30% were male and at least 30% were female.

Diabetics, hypertensive patients were also included in clinical testing. Pregnant women were not included in clinical testing.

The test summary of clinical validation: no safety problems and adverse events were found during the clinical test. The test result show that the Upper Arm Electronic Blood Pressure Monitor (model: A02-SE4 meets the requirement of IEC 80601-2-30:2018 and ISO 81060-2:2018.

12. Disposal

Dispose of at public collection point in the EU countries–2002/96/EC WEEE Directive.

Dispose of your monitor and other components according to applicable local regulations.

Unlawful disposal may cause environmental pollution.

Disposal of used batteries should be carried out in accordance with local regulations.

13. 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.

Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This product 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 product 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 product 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.

FCC RF Exposure Information and Statement:

When carrying the product or using it while worn on your body, either use an approved accessory such as a holster . Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

14. Electromagnetic Compatibility

Statement:

The equipment with following ESSENTIAL PERFORMANCE is intended used in Home healthcare environment and professional healthcare facility environment.

Essential Performance:

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

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

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

Warning：

- Using cell phone or microwave oven, HF surgical equipment, magnetic resonance imaging or other radio radiant equipment near this product may cause malfunction or lead to loss of essential performance, which means that the measurement accuracy will be affected.
- 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.
- 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 monitor. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories, transducers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Caution:

- Security, antitheft, and radiofrequency identification (RFID) devices. Some electromagnetic anti-theft systems and metal detectors such as those used at entrances or exits of department stores, libraries, and other public places, and airport security screening devices may affect the monitor. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect the monitor. Please do not use monitor near these places. If you have to go through one of these devices, turn off your monitor. Before each usage, checking the status of your monitor to ensure it can operating normally.
- Using short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) and electrocautery devices near this product may cause malfunction or lead to loss of essential performance, please do not use monitor near these equipment. Before each usage, observing the device to verify that they are operating normally.

A list of cables and maximum length of cables is as follows:

Cables name	Cable length	Whether shielding
TYPE-C Cable	1000mm±30mm	No

Guidance and manufacture’s declaration – electromagnetic emission

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

Guidance and manufacture's declaration – electromagnetic immunity			
The Blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood pressure monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge IEC 61000-4-2	±8kV contact; ±2kV, ±4kV, ±8kV, ±15 kV air	±8kV contact; ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM fields IEC 61000-4-3	3V/m 80MHz-2.7GHz 80%AM at 1kHz or 2Hz	10V/m (Home healthcare environment) 80MHz – 2.7GHz 80% AM at 1kHz or 2Hz	power quality should be that of a HOME HEALTHCARE ENVIRONMENT and Professional healthcare facility environment.
Electrical fast transients/bursts IEC 61000-4-4	±2kV AC power supply lines; ±1kV DC power/Signal lines. 100 kHz repetition frequency	±2kV AC power supply lines;	power quality should be that of a HOME HEALTHCARE ENVIRONMENT and Professional healthcare facility environment.

Surges IEC 61000-4-5	±0.5kV, ±1kV lines to lines; ±0.5kV, ±1kV, ±2kV lines to earth	±0.5kV, ±1kV lines to lines;	power quality should be that of a HOME HEALTHCARE ENVIRONMENT and Professional healthcare facility environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3V 0.15MHz – 80MHz, 6V in ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz	3V 0.15MHz – 80MHz, 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	power quality should be that of a HOME HEALTHCARE ENVIRONMENT and Professional healthcare facility environment.
Note: The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.			

Rated power frequency magnetic fields IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz	Power frequency magnetic fields should be at levels characteristic of a HOME HEALTHCARE ENVIRONMENT and Professional healthcare facility environment.
Voltage dips IEC 61000-4-11	0% U_T, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% U_T, 1 cycle and 70% U_T, 25/30 cycle Single phase: at 0°	Applicable	power quality should be that of a HOME HEALTHCARE ENVIRONMENT and Professional healthcare facility environment.
Voltage interruptions IEC 61000-4-11	0% U_T, 250/300 cycle	Applicable	
NOTE: U_T is the a.c. mains voltage prior to application of the test level. E.g.: 25/30 means 25 periods at 50 Hz or 30 periods at 60 Hz.			

Guidance and manufacture's declaration – electromagnetic immunity			
The Blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood pressure monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See the following table	Complies	
Proximity magnetic fields IEC 61000-4-39	See the following table	Complies	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation**	**Immunity Test Level** (V/m)
385	380 – 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1 720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5 240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5 500				
5 785				

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

Test specifications for enclosure port immunity to proximity magnetic files

Test frequency	Modulation	Immunity test level (A/M)
30 kHz[a)]	CW	8
134.2 kHz	Pulse modulation[b)] 2.1 kHz	65[c)]
13.56 MHz	Pulse modulation[b)] 50 kHz	7.5[c)]
a)This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the home healthcare environment. b)The carrier shall be modulated using a 50% duty cycle square wave signal. c)r.m.s, before modulation is applied		

15. Reporting adverse events

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

1) **Report Online** at: www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

2) **Consumer Reporting Form FDA 3500B**. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatch*Learn*. The form is available at: www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

3) **Call FDA at 1-800-FDA-1088** to report by telephone

a) **Reporting Form FDA 3500** commonly used by health professionals. The form is available at: www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

16. Travel or international use statement

Since the accuracy of the Upper Arm Electronic Blood Pressure Monitor will be affected by the external environment, in view of the uncertainty and instability of the travel environment, please do

not use the Electronic Upper Arm Electronic Blood Pressure Monitor during travel or on the aircraft. The Upper Arm Electronic Blood Pressure Monitor can be internationally used, but it must be used and stored in the environment specified in this user manual, and please make sure the input power of your AC adapter is AC 100~240V 50/60 Hz and output power is USB 5V 600mA, and please make sure your have a converter to convert to the proper voltage of the target country. To ensure that the Electronic Upper Arm Electronic Blood Pressure Monitor is not affected during carrying, please check the following items before use to ensure it can operating normally:

- Check the monitor to ensure that the main unit and cuff are free from damage and cracks.
- Check whether the battery is leakage, If there is leakage, please replace the battery.
- Check whether the display is normal and without E-X(X stands for Arabic numerals) prompt.

If there are any abnormality, please stop using.

17. Warranty

- The unit is guaranteed to be free of defects in workmanship and materials under normal use for a period of Five Years from the date listed on the purchase record.
- For repair under this warranty, our authorized service agent must be advised of the fault with the period of the warranty. This warranty covers parts and labor only under normal operations. Any defect resulting from natural causes (e.g., flood, hurricane, etc.) is not within this guarantee.
- This guarantee does not cover damage incurred by use of the unit not in accordance with the instructions, accidental damage, or being tampered with or serviced by unauthorized service agents.
- Monitor subjected to misuse, abuse, and neglect of this manual's content, non-instructional purposes, unauthorized repair or modifications will be excluded from this warranty.

18. Manufacturer information:

ShenZhen GoodlyMed Technology Co.,Ltd.

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