

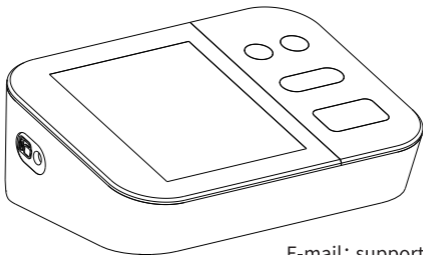
# Fully Automatic Upper Arm Blood Pressure Monitor

Model Number: 111

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## USER'S MANUAL

- 2\*99Memory
- Average
- Date / Time



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Website: [4aile.com](http://4aile.com)

### **A Special Thank You...**

Thank you for choosing a 111 blood pressure instrument. We're proud of the care and quality that goes into the manufacture of each and every item that bears our name. Only the finest materials are used to assure you of a timeless instrument designed for optimum performance. You'll quickly appreciate the results, for you now own one of the finest digital blood pressure instruments that money can buy. With proper care and maintenance, your 111 automatic blood pressure monitor is sure to provide you with many years of dependable service. Please read the following instructions and general information which will prove helpful in allowing you to enjoy your 111 of Digital In hospitals and physician's offices throughout the world, where accuracy and dependability are critical, 111 professional diagnostic products are the instruments of choice.

Now you too can enjoy the benefits of 111 engineering and quality in the home. This feature rich instrument was designed to simplify the measurement of blood pressure and pulse rate at home and deliver consistent, dependable results. Your 111 digital blood pressure monitor is a fully automatic digital blood pressure measuring device for use on the upper arm. It enables very fast and reliable measurement of the systolic and diastolic blood pressure as well as the pulse by way of the oscillometric method. This device offers accuracy and has been designed to be user friendly. Read this booklet thoroughly before attempting to use your new 111 Digital Blood Pressure Monitor.

Thank you for your patronage. It is indeed our pleasure to serve you.

Sincerely,

Shenzhen Yuezhongxing Technology Co., Ltd.



**Shenzhen Yuezhongxing Technology Co., Ltd.**

No.2 Zhenye Road, Pingshan District, Shenzhen, China

Contact: support@4aile.com

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## **1. INSTRUCTION AND INTENDED USE**

This manual is for the 111 models. It is a fully automatic digital blood pressure measuring device for use by adults on the upper arm at home or in your doctor's/nurse's office.

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with arm circumference ranging from (□22-42cm □22-52cm).

The devices detect the appearance of irregular heartbeats during measurement

It enables very fast and reliable measurement of systolic and diastolic blood pressure as well as pulse through the oscillometric method. This device offers clinically proven accuracy and has been designed to be user friendly. Before using, please read this instruction manual carefully and then keep it in a safe place. Please contact your doctor for further questions on the subject of blood pressure and its measurement.

The user is an intended operator, the functions of monitoring blood pressure and pulse rate can be safely used by user. The routine clean and changing batteries can be performed by the user.

## Contraindication(s)

Use of this instrument on patients under dialysis therapy or on anticoagulant, antiplatelets, or steroids could cause internal bleeding.

## intended patient population

This monitor is intended for use by adults only. Consult with a physician before using this instrument on a child.

## Intended placement of cuff

Place the cuff on your bare upper arm one inch above the bend of your elbow. Make sure the tubing falls over the front center of your arm so that the sensor is correctly placed. Pull the end of the cuff so that it's evenly tight around your arm.

## Warning:

- When patient use this device by themselves, the PATIENT is an intended OPERATOR.
- Do not service or maintain while this device is in use.
- All functions can be safely used by patient.
- Patient can perform the maintenance: changing batteries and cleaning.
- DO NOT use this monitor on infants, toddlers, children or persons who cannot express themselves.
- DO NOT use this monitor on an injured arm or a arm under medical treatment.
- DO NOT apply the arm cuff on your arm while 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.

- 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; preeclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.
- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- Consult with your physician before using this monitor on a wrist 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.
- 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 take measurements more often than necessary because bruising, due to blood flow interference, may occur.
- ONLY inflate the arm cuff when it is applied on your arm.
- Remove the arm cuff if it does not start deflating during a measurement.
- DO NOT use this monitor for any purpose other than measuring blood pressure.
- During measurement, make sure that no mobile device or any other electrical device that emits electromagnetic fields is within 12 inches (30cm) of this monitor. This may result in incorrect operation of the monitor and/or

cause an inaccurate reading.

- 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 this monitor in places with high or low humidity or high or low temperatures.
- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.
- DO NOT use this monitor in high-use environments such as medical clinics or physician offices.
- 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.
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.
- Rest for at least 5 minutes before taking a measurement.
- Remove tight-fitting, thick clothing and any accessories from your wrist while taking a measurement.
- Remain still and DO NOT talk while taking a measurement.
- ONLY use this monitor on persons whose wrist circumference is within the specified range of the cuff.
- Ensure that this monitor has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading. We recommend waiting for approximately 2 hours for the monitor to warm up or cool down when the monitor is used in an environment within the temperature


specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information of operating and storage/transport temperature.

- DO NOT crease the arm cuff excessively.
- DO NOT use this monitor after the durable period has ended. Never apply the arm cuff over a wound, as this can cause further injury;
- No modification of this equipment is allowed.
- Do not modify this equipment without authorization of the manufacturer.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- The time required for the device to warm from the minimum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20 °C .
- The time required for the device to cool from the maximum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20 °C .

**Warning:**

- Use of power adapters
- Adapter: input 100-240v, 50/60hz output DC 5V 1A
- Do not to position the device to make it difficult to operate the disconnection device while using adaptor.
- Do not use cuffs, AC adapters or batteries other than those included with this product or replacement parts supplied by the manufacturer.
- Prone to damage from water leakage, high temperature, moisture, direct sunlight and more or more corrosive gas environment. Avoid using this product in the aforementioned environments.
- Remove the battery if the blood pressure monitor is not likely to be used for

some time.

- Do not use the batteries and the AC adapter to provide power at the same time.
- The separate ac adapter which is intended to connect USB interface of Blood Pressure Monitor has not been evaluated according to IEC 60601-1. The safety of the product shall be reappraised when it power supply by a separate ac adapter.
- DO NOT fold or kink the air tube while taking a measurement. This may cause an injury by interrupting blood flow
- Avoid compression and restriction of the connection tubing.
- Please stop using this device and contact distribution or manufacture in the event of changes in the performance of this device.
- Do not use accessories and other parts except for manufacture specified.
- When display "  ", please replace batteries immediately.
- The battery can support to conduct 10 times measurement.
- waiting for approximately 2 hours for the monitor to warm up or cool down when the monitor is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature.
- This device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens) during use. These can lead to erratic results.
- Do not attempt to service or repair this device yourself. Should a malfunction occur, refer to local distributor or the manufacturer.
- Significant risks of reciprocal interference posed by me equipment during specific investigations or treatments.

**Note:** To obtain the greatest accuracy from your blood pressure instrument, it is recommended that the instrument be used within the specified temperature and the relative humidity, please see the Technical Specifications.

**Note:** The cuff is treated as the applied part. The user should contact the manufacturer for assistance, if needed, in setting up, using or maintaining the device. The standard material used for the bladder and tubing is latex-free.

**Attention:** Self-measurement means control, not diagnosis or treatment. Unusual values must always be discussed with your doctor. Under no circumstances should you alter the dosages of any drugs prescribed by your doctor. The pulse monitoring function is not suitable for checking the frequency of heart pacemakers!

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## **2. IMPORTANT INFORMATION ON BLOOD PRESSURE AND ITS MEASUREMENT**

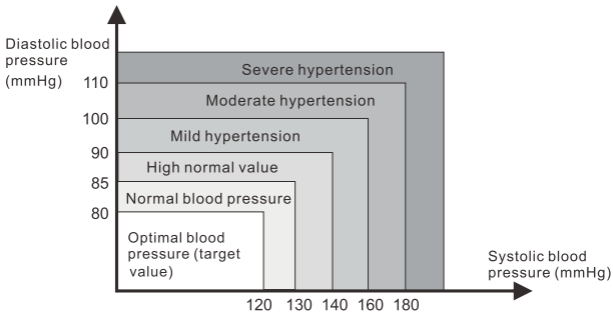
## 2.1 How does high or low blood pressure arise?

Your level of blood pressure is determined in the circulatory center of the brain and adjusts to a variety of situations through feedback from the nervous system. To adjust blood pressure, the strength and speed of the heart (Pulse), as well as the width of circulatory blood vessels is altered. Blood vessel width is controlled by fine muscles in the blood vessel walls. Your level of arterial blood pressure changes periodically during heart activity: During the "blood ejection" (Systole) the value is highest (systolic blood pressure value). At the end of the heart's "rest period" (Diastole) pressure is lowest (diastolic blood pressure value).

Blood pressure values must lie within certain normal ranges in order to prevent particular diseases.

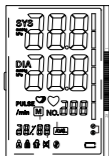
## 2.2 WHICH VALUES ARE NORMAL

Please refer to the diagram below(Picture-01)



Picture-01

There are six grids in the display of device. Please refer to the picture-01-01. Different grids represent different interval scales of WHO.



Blood pressure value	WHO grids in device	WHO Classification
DIA < 80 & SYS < 120	1	Optimal blood pressure
DIA < 85 & SYS < 130	2	Normal blood pressure
DIA < 90 & SYS < 140	3	High normal value
DIA < 100 & SYS < 160	4	Mild hypertension
DIA < 110 & SYS < 180	5	Moderate hypertension
DIA ≥ 110 or SYS ≥ 180	6	Severe hypertension

picture-01-01

Blood pressure is very high if your diastolic pressure is above 90 mmHg and/or your systolic blood pressure is over 160 mmHg, while at rest. In this case, please consult your physician immediately. Long-term values at this level endanger your health due to continual damage to the blood vessels in

your body. If your systolic blood pressure values are between 140 mmHg and 159 mmHg and/or the diastolic blood pressure values between 90 mmHg and 99 mmHg, consult your physician. Regular self-checks are necessary. If you have blood pressure values that are too low, (i.e., systolic values under 90 mmHg and/or diastolic values under 60 mmHg), consult your physician. Even with normal blood pressure values, a regular self-check with your blood pressure monitor is recommended. You can detect possible changes in your values early and react appropriately. If you are undergoing medical treatment to control your blood pressure, keep a record of values along with time of day and date. Show these values to your physician. Never use the results of your measurements to independently alter the drug doses prescribed by your physician.

The method of verifying the calibration of blood pressure monitor in pressure gauge test mode:

Step 1: blood pressure monitor in time mode, long press the setting key and then press the memory key to enter the static pressure mode.

Step 2: connect the special plug with the windpipe and insert the blood pressure monitor armband interface with the equipment integrated with the gas source and the manometer. The static pressure of the instrument is displayed in the high pressure area. Comparing the pressure displayed by the device with the pressure shown by the manometer, the difference is less than 3mmHg as qualified.

### **Further information**

- If your values are mostly normal under resting conditions but exceptionally high under conditions of physical or psychological stress, it is possible that you



are suffering from so-called "labile hypertension." Consult your doctor.

- Correctly measured diastolic blood pressure values above 120mmHg require immediate medical treatment.

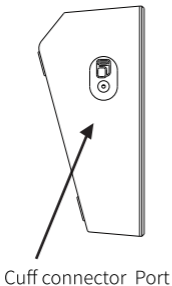
## 2.3 What can be done if regular high or low values are obtained?

1) Consult your doctor.

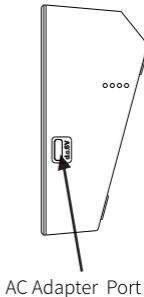
2) Increased blood pressure values (various forms of hypertension) are associated with considerable health risks over time. Arterial blood vessels in vessel walls (Arteriosclerosis). A deficient supply of blood to important organs (heart, brain, muscles) can result from arteriosclerosis.

Furthermore, the heart will become structurally damaged with increased blood pressure values.

## 3. Components of your blood pressure monitor



Picture-02



Picture-03

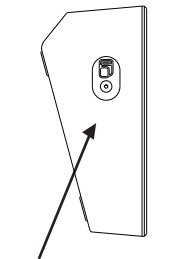
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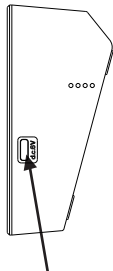
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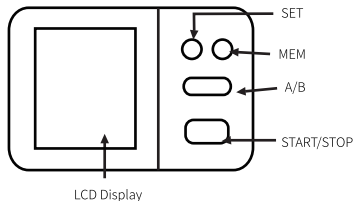
Cuff connector Port

Picture-02



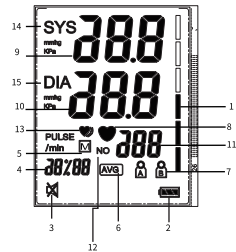
AC Adapter Port

Picture-03



LCD Display

Picture-04



Picture-05

#### 3.2 The symbols on the Picture-05

- |                                     |                              |
|-------------------------------------|------------------------------|
| 1. Blood pressure monitor indicator | 2. Battery symbol            |
| 3. Mute symbol                      | 4. Date/Time display         |
| 5. Memory symbol                    | 6. Average value symbol      |
| 7. USER symbol                      | 8. Heartbeat symbol          |
| 9. Systolic blood pressure          | 10. Diastolic blood pressure |
| 11. Pulse display                   | 12. Number of group symbol   |
| 13. Irregular heartbeat symbol      | 14. Systolic                 |
| 15. Diastolic                       |                              |

#### 3.3 Features of Model 111

- |                                   |                                   |
|-----------------------------------|-----------------------------------|
| 1. Talking function               | 2. Double users: 2*99 sets memory |
| 3. Date/time display              | 4. Irregular heartbeat checking   |
| 5. Average value function         | 6. Low battery display            |
| 7. WHO function                   | 8. Auto power-off                 |
| 9. External power adapter support | 10. Cuff self-checking function   |

Note: Arm circumference should be measured with a measuring tape in the middle of the relaxed upper arm. Do not force cuff connection into the opening. Make sure the cuff connection is not pushed into the AC adapter port.

## **4. Using your Monitor for the First Time**

### **4.1 Activating the pre-installed batteries**

#### Battery Installation

Use only 1.5V "AAA" alkaline batteries with this device.

1. Press the hook on the bottom of the battery cover and lift the cover off in the direction of the arrow.
2. Install 4 "AAA" size batteries so the + (positive) and - (negative) polarities match the polarities of the battery compartment, replace the battery cover. Make sure that the battery cover is securely in position.

#### Battery replacement

##### Low Battery Indicator

1. When the Low Battery Indicator appears on the display, turn the monitor off and remove all the batteries. Replace with 4 new batteries at the same time. Long-life alkaline batteries are recommended.
2. To prevent the damage of monitor from leaked battery fluid, please take out of battery if the monitor unused in a long time (generally more than 3 months). If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Contact a physician immediately.
3. Attached battery is only for testing the function of the monitor, Long-life alkaline batteries are recommended.
4. Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution
5. Battery is dangerous stuff, do not mix it with other rubbish.

### **4.2. System Settings**

After you load the battery or connect power for the monitor, long press the SET button for more than 3 seconds, and then you can start to set when flashing numbers appear on the screen.

#### A. Setting the User:

Press the SET button, then press the USER button. When display A(/B) on the screen, press the USER button to switch to user B(/A).

#### B. Setting the Year:

Press SET button for more than 3 seconds, when the YEAR display is flashing, press MEM button continuously and it will increase continuously 1 by 1 until 2099, once the year set is ok, press SET button to confirm.

#### C. Setting the Month/Date:

After completing the YEAR setting, the MONTH/DATE will flash on the screen, press MEM button, the month will increase by 1, press SET button to confirm. DO the same way to set the Date, press SET button to confirm.

#### D. Setting the Time :

After completing the MONTH/DATE setting, the TIME will flash on the screen, press MEM button, the hour will increase by 1, press SET button to confirm. DO the same way to set the minute, press SET button to confirm.

#### E. Setting the Speaker:

After completing the TIME setting, the SP will flash on the screen, press MEM button to switch ON or OFF, press SET button to confirm.

#### F. Setting the Unit:

The original unit display on the screen is mmHg, after you completing SP setting, the PA will flash on the scree, press MEM button to switch ON, the unit will change from mmHg to kPa.

#### G. Record Delete:

Turn off the machine, press MEM button for 3 seconds, don't let your finger go, press SET button for 3 seconds at the same time, when EEEE appear on the screen, it means the memories have been deleted.

**Note:**

When you choose to delete the records, you will delete all measurement record at one time. If you decide to delete the all record, please keep the record in another way, in case you need it some days later. Take the battery out won't lead to a record missing.

## **5. Measurement Procedure**

**Note:** You should always be seated and calm before and during measurement.

### **5.1 Before measurement**

- Avoid eating and smoking as well as all forms of exertion directly before measurement. These factors influence the measurement result. Find time to relax by sitting in an armchair in a quiet atmosphere for about ten minutes before taking a measurement.
- Remove any garment that fits closely to your upper arm.
- Always measure on the same arm (normally left).
- Always compare measurements taken at the same time of day, since blood pressure changes during the course of the day, as much as 20-40 mmHg.

### **5.2 Common sources of error:**

**Note:** Comparable blood pressure measurements always require the same conditions!

- Conditions should always be quiet.
- All efforts by the user to support the arm can increase blood pressure. Make sure you are in a comfortable, relaxed position and do not flex any of the muscles in the measurement arm during the measurement. Use a cushion for support if necessary.
- If the arm artery lies considerably lower or higher than the heart, an erroneously high or low blood pressure will be measured! Each 25-30cm difference in height between your heart and the cuff results in a measurement error of 10 mmHg!
- Cuffs that are too narrow or too short result in false measurement values. Selecting the correct cuff is extremely important. Cuff size is dependent upon the circumference of the arm (measured in the center). The permissible range is printed on the cuff.

Cuff works Under the pressure range 0-300MMHG

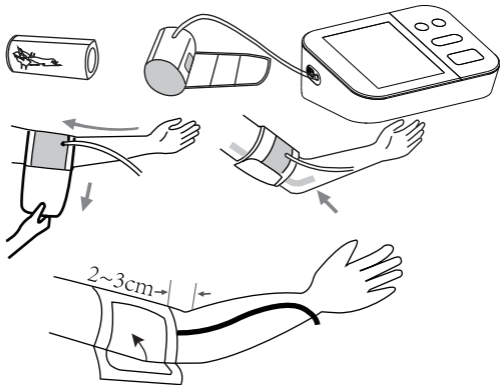
The wide range rigid cuff is:  8.7"-16.5" (22-42 cm)  8.7"-20.4" (22-52 cm)

**Note:** Only use approved cuffs!

- A loose cuff or a sideways protruding air pocket causes false measurement values.
- With repeated measurements, blood accumulates in the arm, which can lead to false results. Consecutive blood pressure measurements should be repeated after a 1 minute pause or after your arm has been held up in order to allow the accumulated blood to flow away. If you decide to take your Averaging Mode measurement again, be sure to wait at least one minute beforehand.

### 5.3 Fitting the Cuff

Please refer to picture-06



Picture-06

- The cuff is preformed for easier use. Remove tight or bulky clothing from your upper arm.
- Wrap the cuff around your upper left arm. The rubber tube should be on the inside of your arm extending downward to your hand. Make certain the cuff lies approximately 1/2" to 3/4" (1 to 2 cm) above the elbow. Important! The on the edge of the cuff (Artery Mark) must lie over the artery which runs down the inner side of the arm.
- To secure the cuff, wrap it around your arm and press the hook and loop closure together.
- There should be little free space between your arm and the cuff. You should be able to fit 2 fingers between your arm and the cuff. Cuffs that don't fit properly result in false measurement values. Measure your arm

circumference if you are not sure of proper fit.

e) Lay your arm on a table (palm upward) so the cuff is at the same height as your heart. Make sure the tube is not kinked.

f) Remain seated quietly for at least two minutes before you begin the measurement.

## **5.4 Measure Procedure**

Refer to picture-07

The monitor is designed to take measurements and store the measurement values in memory for two people using User ID A and User ID B.

1. Sit comfortably in a chair with your feet flat on the floor.
2. Select your User ID (A or B).

Stretch your arm forward on the desk and keep relaxing, make sure the palm of hand is upturned.

Make sure arm is in correct position, to avoid body movement. Sit still and do not talk or move during the measurement. After the cuff has been appropriately positioned on the arm and connected to the blood pressure monitor, the measurement can begin:

- a) Press the START/STOP button. The pump begins to inflate the cuff. In the display, the increasing cuff pressure is continually displayed.
- b) After automatically reaching an individual pressure, the pump stops and the pressure slowly falls. The cuff pressure is displayed during the measurement.
- c) When the device has detected your pulse, the heart symbol in the display begins to blink.
- d) When the measurement has been concluded, the measured systolic and diastolic blood pressure values, as well as the pulse will be displayed.
- e) The appearance of this symbol signifies that an irregular heartbeat was



detected. This indicator is only a caution. It is important that you be relaxed, remain still and do not talk during measurements.

f) The measurement results are displayed until you switch the device off. If no button is pressed for 60 seconds, the device switches off automatically

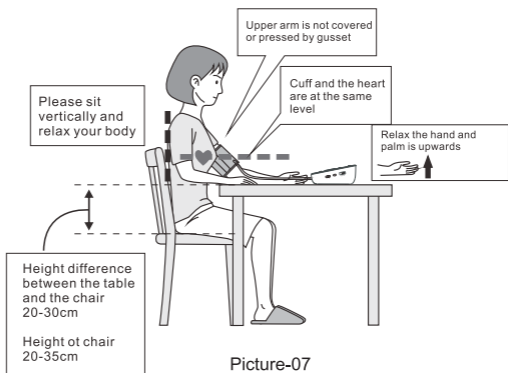
**NOTE:**

Patient Position:

- 1) Comfortably seated
- 2) Legs uncrossed
- 3) Feet flat on the floor
- 4) Back and arm supported
- 5) Middle of the CUFF at the level of the right atrium of the heart

**Recommended Use Methods**

1. Recommendation that the PATIENT relax as much as possible and not talk during the measurement PROCEDURE
2. Recommendation that 5 min should elapse before the first reading is taken
3. Any reading can be affected by the measurement site, the position of the PATIENT, exercise, or the PATIENT'S physiologic condition
4. Performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude
5. To stop the inflation or measurement, push the START/STOP button. The monitor will stop inflating, start deflating, and will turn off.
6. After the monitor has detected your blood pressure and pulse rate, the cuff automatically deflates. Your blood pressure and pulse rate are displayed.
7. The monitor will automatically turn off after one minute.



Picture-07

## 5.5 Irregular Heartbeat Detector

This symbol - indicates that certain pulse irregularities were detected during the measurement.

In this case, the result may deviate from your normal basal blood pressure – repeat the measurement.

Information for the doctor on frequent appearance of the Irregular Heartbeat Symbol.

This instrument is an oscillometric blood pressure monitor device that also analyzes pulse frequency during measurement. The instrument is clinically tested. If pulse irregularities occur during measurement, the irregular heartbeat symbol is displayed after the measurement. If the symbol appears more frequently (e.g. several times per week on measurements performed daily) or if it suddenly appears more often than usual, we recommend the patient to seek medical advice. The instrument does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

## 5.6 Error Indicates

The following symbol will appear on the display when measuring abnormal

SYMBOL	CAUSE	CORRECTION
Er 1	Sensor abnormal	1. Don't talk or shake your arm before measuring; 2. Check if the pump is working or not.
Er 2	Blood pressure can't be measured	Check the wearing position of the cuff and remeasure according to the required posture.
Er 3	Blood pressure is abnormal	Check the wearing position of the cuff and remeasure according to the required posture
Er 4	Blood pressure arm cuff cannot be pressurized	1. Check whether the air path is open; 2. Check whether the arm cuff is too loose.
Er 5	Arm cuff is pressurized too fast	1. Check whether any blockage in the air path; 2. Check whether the arm cuff is too tight.
Er 6	Excessive pressure interference	Measure the posture according to the requirements. DO NOT move your body in the measurement.
Er 7	The pressure exceeds the limit	Measure the posture according to the requirements. DO NOT move your body in the measurement.

## Trouble Removal









PROBLEM	CHECK	CAUSE AND SOLUTION
No power	Check the battery power	Replace new one
	Check the polarity position	Installation for proper placement of the batteries polarities

No inflation	Whether the plug insert	Inset into the air socket tightly
	Whether the plug broken or leak	Change a new cuff
Err and stop working	Whether move the arm when inflate	Keep the body peaceful
	Check if chatting when measured	Keep quite when measure
Cuff leak	Whether the cuff wrap too loose	Wrap the cuff tightly
	Whether the cuff is broken	Change a new cuff
Please contact the distributor if you can't solve the problem, do not disassemble the unit by your self		

## SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the Digital Blood Pressure Monitor 111, or on it's accessories. Some of the symbols represent standards and compliances associated with the Digital Blood Pressure Monitor 111 and its use.

	Authorized Representative in the European Community
	CE Mark: conforms to essential requirements of the Medical Device Regulation 2017/745
	Date of manufacture
	Manufacturer
	Specifies serial number
	Direct current
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary
	Follow instructions for use
	Put up

	Fragile
	Keep dry
	Avoid the sun
	Temperature range
	Follow instruction for use
	Type BF Applied Part
	Indicates separate collection for waste of electrical and electro-nic equipment(WEEE)
	Use-by date, indicating the date after which the device is not to be use(i.e;the expiration date)
<b>IP22</b>	Degrees of protection provided by enclosure

## 5.7. Memory

At the end of a measurement, this monitor automatically stores each result with date and time. Each unit stores 99 sets measurements for 2 users, totally 198 sets (User A and B)

### Viewing the stored values

With the unit off, press the Memory button. The display first shows "A", then shows an average of all measurements stored in the unit. Please note: Measurements for each user are averaged and stored separately. Be certain that you are viewing the measurements for the correct user. Pressing the Memory button again displays the previous value. To view a particular stored memory, press and hold the Memory button to scroll to that stored reading.

## 5.8. 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 then immediately lowers the cuff pressure automatically.

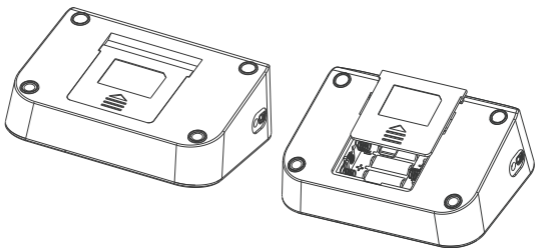
## 5.9. Battery Change Indicator

### Batteries discharged– replacements required

When the batteries are discharged, the battery symbol will flash as soon as the instrument is switched on. You cannot take any further measurements and must replace the batteries.

The battery compartment is located on the back side of the unit.

- Remove cover from the bottom plate, as illustrated below picture-08
- Insert the batteries (4 x size AAA ). Always use AAA long life batteries or alkaline 1.5v batteries.
- The memory retains all values although date and time must be reset - the year number therefore flashes automatically after the batteries are replaced.
- To set date and time, follow the procedure described in Section 4.2.



### **Which batteries and which procedure?**

Use four new, longlife 1.5V AAA batteries. Do not use batteries beyond their expiration date. If the monitor is not going to be used for a prolonged period the batteries should be removed

### **Using rechargeable batteries**

You can also operate this instrument using rechargeable batteries.

- Only use "NiMH" reusable batteries!
- If the battery symbol the batteries must be removed and recharged! They must not remain inside the instrument, as they may become damaged through total discharge even when switched off. The batteries must NOT be discharged in the blood pressure monitor! If you do not intend to use the instrument for a week or more, always remove the rechargeable batteries!
- Recharge these batteries using an external charger and follow manufacturer's instructions carefully.

### **5.10. Using the AC Adapter**

You may also operate this monitor using the AC adapter (output 5V DC/1A with Micro USB plug).

Use only the approved AC adapter to avoid damaging the unit.

- a) Ensure that the AC adapter and cable are not damaged.
- b) Plug the adapter cable into the AC adapter port on the right side of the blood pressure monitor.
- c) Plug the adapter into your electrical outlet. When the AC adapter is connected, no battery current is consumed.

Note: No power is taken from the batteries while the AC adapter is connected to the monitor. If electrical power is interrupted, (e.g., by accidental removal of the AC adapter from the outlet) the monitor must be reset by removing the plug from the socket and reinserting the AC adapter connection.

## **6. Care and Maintenance**

Wash hands after each time measurement.

If one device is used by different patients, wash hands before and after each use.

- a) Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.
- b) The cuff contains a sensitive air-tight bubble. Handle this cuff carefully and avoid all types of stress through twisting or buckling.
- c) Clean the device with a soft, dry cloth. Do not use gas, thinners or similar solvents. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff with bladder must not be washed in a dishwasher, clothes washer, or submerged in water.
- d) Handle the tube carefully. Do not pull on it. Do not allow the tubing to kink and keep it away from sharp edges.
- e) Do not drop the monitor or treat it roughly in any way. Avoid strong vibrations.
- f) Never open the monitor! This invalidates the manufacturer's warranty.
- g) Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

### **6.1. Accuracy Test**

Sensitive measuring devices must be checked for accuracy from time to time.

We recommend a periodical inspection of your unit by an authorized dealer every 1 year. Please turn to local distributor or the manufacturer.

### **7. Warranty**

Your blood pressure monitor is guaranteed for 1 year against manufacturers' defects for the original purchaser only, from date of purchase. The warranty does not apply to damage caused by improper handling, accidents,



professional use, not following the operating instructions or alterations made to the instrument by third parties.

Warranty only applies to the instrument. All accessories including the cuff are guaranteed for one year, USB charging cable is not included.

There are no user serviceable parts inside. Batteries or damage from old batteries is not covered by the warranty.

Note: According to international standards, your monitor should be checked for accuracy every year.

## **8. Certifications**

Device standard:

This device is manufactured to meet the European blood pressure monitors: EN ISO 81060-1 :2007 • IEC 80601-2-30 • IEC60601-1-11 • IEC60601-1

Electromagnetic compatibility:

Device fulfills the stipulations of the International standard IEC60601-1-2

## **9. Technical Specifications**

Model: 111

Weight: 270g (Batteries and AC adapter are not included)

LCD Digital Display Size: 76 (W) x 62 (L) x 2.8 (H) mm 【  
3"(W)x2.44"(L)x0.11"(H)】

Accessories: 1×Main Device, 1×Cuff, 1×Users manual, 1×Warranty card

Operating Conditions: Temperature: 5°C to 40°C; Humidity: 15% to 93% RH;

Storage And Shipping Conditions: Temperature: -25°C to 70°C; Humidity: ≤ 93% RH;

Atmospheric pressure range: 70kPa~106kPa

Measuring method: Oscillometric

Pressure sensor: Resistive

Measuring range: 0-280mmHg;

Blood pressure detection range: systolic blood pressure 55-255mmHg, diastolic blood pressure 25-200mmHg

Pulse: 40 to 199 per minute

Cuff pressure display range: <300mmHg

Memory: Automatically stores the last 99 measurements for 2 users (total 198)

Measuring resolution: 1 mmHg

Accuracy: Pressure within  $\pm 3$  mmHg / pulse  $\pm 5$  % of the reading

Power source: a) 4\*AAA batteries, 1.5 V b) AC adapter INPUT: 100-240VAC

50/60HZ OUTPUT: 5V DC 1A

Accessories: Wide range rigid cuff □8.7"-16.5" (22-42 cm) □8.7"-20.4" (22-52 cm)

Automatically power off : 60 seconds

Users: Adult

Expected service life of the device and accessories: 5 years

Technical alterations reserved!

The SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013

## **10. EMC Declaration**

1) \*This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

2) \* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

3) \* Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!


4) \* Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used

<b>Guidance and manufacture's declaration - electromagnetic immunity</b>			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD)  IEC 61000-4-2	$\pm 8$ kV contact  $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV,  $\pm 15$ kV air	$\pm 8$ kV contact  $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV,  $\pm 15$ kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst  IEC 61000-4-4	$\pm 2$ kV for power supply lines  $\pm 1$ kV for input /output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge  IEC 61000-4-5	$\pm 1$ kV line(s) to line(s)  $\pm 2$ kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

<p>Voltage dips, short interruptions and voltage variations on power supply input lines</p> <p>IEC 61000-4-11</p>	<p>0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°</p> <p>0 % UT ; 1 cycle</p> <p>70 % UT; 25/30 cycle</p> <p>0% UT; 250/300 cycle</p> <p>t 0°</p> <p>0 % UT; 250/300 cycle</p>	<p>Not applicable</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the W203 blood pressure monitor requires continued operation during power mains interruptions, it is recommended that the W203 blood pressure monitor be powered from an uninterruptible power supply or a battery.</p>
<p>Power frequency (50/60 Hz) magnetic field</p> <p>IEC 61000-4-8</p>	<p>30 A/m</p> <p>50/60Hz</p>	<p>30 A/m</p> <p>50/60Hz</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>NOTE UT is the a. c. mains voltage prior to application of the test level.</p>			

**Guidance and manufacturer's declaration – electromagnetic immunity**

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF  IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 3 V RMS outside the ISM band, 6 V RMS in the ISM and amateur bands 80% AM at 1kHz		Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=0.35\sqrt{p}$ $d=1.2\sqrt{p}$
Radiated RF  IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	80MHz to 800MHz: $d=1.2\sqrt{p}$ 800MHz to 2.7GHz: $d=2.3\sqrt{p}$ Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance.  Field strengths from fixed RF transmitters, as determined

Test frequency (MHz)	Band (MHz)	Service (MHz)	Modulation	Maximum power(w)	Distance (m)	IMMUNITY TEST
385	380-390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-19	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3 4,25;UMTS	Pulse Modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400-25 7090	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28

			<p>by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</p>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>A. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment</p>			
<p>to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.</p> <p>B. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			
<p><b>Guidance and manufacture's declaration - electromagnetic emission</b></p>			
<p>The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.</p>			

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2,3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

#### **Guidance and manufacture's declaration - electromagnetic immunity**

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device, should assure that it is used in such an environment.



Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device use 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 device is suitable for use in all establishments, including domestic establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

5240	5100-5800	WLAN	Pulse Modulation 217 Hz	0.2	0.3	9
5500		802.11				
5785		a/n				

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. 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS

shall be calculated using the following equation:

$$E = \frac{6}{d} \sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

## 11. Warranty Card

The First Repair	Faults	Reasons	What is Repaired
	Date: _____ Repaired by: _____		
The Second Repair	Faults	Reasons	What is Repaired
Date: _____ Repaired by: _____			

Blood pressure is very high if your diastolic pressure is above 90 mmHg and/or your systolic blood pressure is over 160 mmHg, while at rest. In this case, please consult your physician immediately. Long-term values at this level endanger your health due to continual damage to the blood vessels in your body. If your systolic blood pressure values are between 140 mmHg and 159 mmHg and/or the diastolic blood pressure values between 90 mmHg and 99 mmHg, consult your physician. Regular self-checks are necessary. If you have blood pressure values that are too low, (i.e., systolic values under 90 mmHg and/or diastolic values under 60 mmHg), consult your physician. Even with normal blood pressure values, a regular self-check with your blood pressure monitor is recommended. You can detect possible changes in your values early and react appropriately. If you are undergoing medical treatment to control your blood pressure, keep a record of values along with time of day and date. Show these values to your physician. Never use the results of your measurements to independently alter the drug doses prescribed by your physician.

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