

Upper Arm Blood pressure Monitor

User Manual

Model:SP10A/SP10B/SP10C

Table of Contents

Foreword.....	3
Intended use	3
Intended users	3
1, Warning instructions and precautions	3
2, Blood pressure and self-measurement.....	6
3, HOW TO EVALUATE YOUR BLOOD PRESSURE	7
4, Product introduction	8
5 Charging battery	11
6.Directions for use.....	12
7. Clean the monitor and cuff.....	24
8. Calibration and maintenance	25
9. Error indicators and troubleshooting.....	25
10.Storage	26
11 . Standard list	26
12 . Disposal	27
13 . NORMALIZED SYMBOLS.....	27
14. Package list	28
15.Electromagnetic Compatibility	28
16.After-sales service	33
17.FCC compliance statement	34
Warranty Card.....	34

Foreword

Thank you for purchasing the Upper Arm Blood pressure Monitor. The blood pressure monitor uses the oscillometric method of blood pressure measurement. This means the monitor detects your blood's movement through your brachial artery and converts the movements into a digital reading. An oscillometric monitor does not need a stethoscope so the monitor is simple to use.

The Upper Arm Blood pressure Monitor was clinically investigated according to the requirements of ISO 81060-2

Please read this instruction manual thoroughly before using the unit.

Please keep for future reference.

For specific information about your own blood pressure, CONSULT YOUR DOCTOR.

Intended use

The Upper Arm Blood pressure Monitor is intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual.

Measurement environment: hospital and home.

Intended placement of the cuff: upper left arm.

Intended users

1. Adult
2. Have 9 years intensive reading experience
3. Can be read and understand the user manual
4. The device can be used by non-professionals, users should consult medical professionals.

1, Warning instructions and precautions

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/precautions symbols	
	Warning: Means a possibility of personal injury in case of improper use.
	Caution: Means a possibility of personal injury or property damage in case of improper use.
	PROHIBITION Means Forbidden with detailed items expressed in words or figures within or beside the mark. Left one means General Forbidden.
	Represents enforcement (what must be obeyed). Specific mandatory content is represented in or near  by text or graphics: "general mandatory"

Read and save these instructions



Before using your blood pressure monitor, please read this instructions and warnings completely.



Warning

For proper use of this product, please follow the warning information listed below:

Cautions for power source	◎ If the LCD displays a low voltage symbol, please charge it immediately. ● So as not to affect the use and damage the battery. ◎ Please unplug the power supply when fully charged. ● Otherwise, the monitor may be damaged. ◎ Please do not disassemble and replace the rechargeable battery by yourself. Please contact the manufacturer when need to replace it. ● Otherwise, the monitor may be damaged.	 PROHIBITION
	◎ Please use the DC 5V1A standard power plug for charging and firmly plug it into the socket. ● Otherwise, there may be risks such as electric shock, short circuit and fire. ◎ When unplugging the adapter, do not unplug the power cord, but unplug it from the connector end. ● The breakage or short circuit of the power cord may cause fire and electric shock. ◎ When using USB power cord, please pay attention to the following matters (avoid damage/do not process/do not bend or stretch hard/do not squeeze/do not place heavy objects on it/do not bind/twist when using). ● Otherwise, it may cause fire or electric shock. ◎ Please unplug the power plug before servicing this product. ● Otherwise, there will be danger of electric shock and injury. ◎ When the monitor does not respond or feel abnormal after being connected to the power supply, please stop using it immediately and remove the charging cable for inspection. Do not charge for a long time at night. ● Otherwise, there may be risks such as electric shock, short circuit and fire. ◎ Do not charge in thunderstorm. ● Otherwise, the monitor may be damaged. ◎ When the product is not used for a long time, the battery will discharge slowly. In order to avoid battery damage due to low voltage for a long time, please charge the device for every three months; store and use the device in an environment specified in this user manual, do not store or use it in high temperature, damp and easy falling environment. ● Otherwise, the device may be damaged.	 Enforcement
Measurement process	◎ When the air bag is persistently overinflated, or if you feel uncomfortable during the measurement, you must stop the blood pressure measurement! You can press the user 1 of user 2 key, the blood pressure monitor will immediately release the air in the armband. ● Otherwise, it may result in blood flow block and limb injury.	 Enforcement

	⦿ Do not measure blood pressure when common arrhythmias occur. ● Measurements may not be accurate or blood pressure may not be measured. ⦿ it is dangerous for patients to self-judge and self-treat according to measuring results, so please follow your doctor's instructions. ● Self-judgment may make the illness worse. ⦿ Do not use this product for newborns or infants and people who cannot express themselves, ● Otherwise, it may become the cause of accidents or disputes. ⦿ patients with serious blood circulation disorders, blood diseases, please use under the guidance of the doctor. ● Pressure on the arm during measurement may result in acute internal hemorrhage. ⦿ Do not apply of the cuff and its pressurization on any limb where intravascular access or therapy, or an arterio-venous(A-V) shunt is present. ● Temporary interference with blood flow and could result in injury to the patient. ⦿ noninvasive blood pressure (NIBP) should not be measured in patients with sickle cell disease or in patients with skin lesions in extremities where blood pressure is measured. ● Otherwise, the injury may be aggravated. ⦿ Do not wrap the cuff around the arm for intravenous drip and blood transfusion. ● Otherwise, symptoms may worsen.	
Other Cautions	⦿ Do not disassemble or repair or modify the main unit and cuff of the blood pressure monitor. ● Otherwise it cannot be measured correctly.	 Prohibition of disassembly
	⦿ Please use according to the description of this manual, and the storage temperature and humidity standard, use the original cuff. ● Otherwise, it may not be measured correctly. ⦿ Please be sure to use the original cuff and specified other parts of this product. ● Otherwise it may not be measured correctly.	 Enforcement
	⦿ Do not use the mobile phone near the product or place the product in the electromagnetic field when using the product. ● Otherwise it cannot be measured correctly. ⦿ Do not use the device in the area of HF surgical equipment, MRI, or CT scanner, or in an oxygen rich environment. ● Otherwise it cannot be measured correctly. ⦿ Do not use the blood pressure monitor while walking or on moving vehicles (such as cars, airplanes, etc.). ● Otherwise it cannot be measured correctly. ⦿ Do not place cuff on a limb with an intravenous infusion or intubation. This can cause fluid flow to slow down or become blocked while the cuff is inflated. ● May cause tissue damage around the catheter. ⦿ Do not use this product in airplanes or hospitals where the use of wireless equipment is prohibited.	 PROHIBITION

Other Suggestions:

- ※ this product will not interfere with the surrounding electrical and electronic products.
- ※ this product is not allowed to be tested and maintained on site. If there is any problem, please directly contact the company according to the contact information in this manual.
- ※ hint: any blood pressure measurement is influenced by the person's posture and his/her physical condition. Other factors that interfere with blood pressure measurement are: season, temperature, mood, environment, etc.
- ※ this product only plays an auxiliary role in the diagnosis of patients. Please ask a doctor to make a diagnosis based on clinical manifestations and symptoms.
- ※ DO NOT adjust medication based on measurement values from this blood pressure monitor. Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat High Blood Pressure.
- ※ the blood pressure has sensitive electronic components, so avoid using it in an environment with electromagnetic interference (such as near a mobile phone or microwave oven).
- ※ Do not forcibly crease the arm cuff or the air tube excessively, continuous cuff pressure may lead to blood flow interference and result in harmful injury to the patient.
- ※ The pressurization of cuff can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb.
- ※ The operation of the AUTOMATED SPHYGMOMANOMETER does not result in prolonged impairment of the circulation of the blood of the patient.
- ※ Too frequent measurements can cause injury to the patient due to blood flow interference.
- ※ Do not apply of the cuff and its pressurization on the arm on the side of mastectomy or lymph node clearance.
- ※ Do not apply of the cuff over a wound, as this can cause further injury.
- ※ Do not press the air tube while taking a measurement.
- ※ Do not drop the monitor or subject device to strong shocks or vibrations.
- ※ Do not inflate the arm cuff when it is not wrapped around your arm.
- ※ Do not use the device outside the specified environment. It may cause an inaccurate reading.
- ※ Please keep the unit out of reach of children.

Side effect

Too frequent measurement, too short pressure interval and too long-time measurement will cause limb ischemia, numbness, compartment syndrome, purpura and other complications.

2, Blood pressure and self-measurement

Blood pressure is the pressure placed on blood vessels by the beating heart as it pushes blood through them. Systolic (high) blood pressure and diastolic (low) blood pressure are usually measured.

The blood pressure monitor also measures the number of heart rate (beats per minute of the heart). Long-term high blood pressure is harmful to health and must be consulted and treated by a doctor. If abnormal values are found, consult your doctor, but do not rely on single measurement alone.

Some factors can affect the accuracy of blood pressure measurements. Wrist blood pressure measurements are sometimes different from arm blood pressure measurements, so it is recommended to compare the results of the two products and consult your doctor.

Blood pressure can vary depending on your condition. Therefore, please take your blood pressure measurement in a quiet and relaxing environment. At least twice a day, once in the morning and once in the evening. It is normal for blood pressure measured by a doctor or at a pharmacy to be different from that measured at home, depending on the environment in which it is measured.

Multiple measurements were more reliable than single measurements, the interval between the two measurements should be at least 2 minutes. Pregnant women should be especially careful to measure blood pressure, because pregnant women's blood pressure changes more than normal person.

If you are suffering from arrhythmia, the measurement value of blood pressure monitor should be used as reference and assessment.

The following conditions may cause changes in blood pressure measurements: within an hour of eating; After drinking, coffee or black tea; Talking during measurement; When nervous or emotionally unstable; measurement with the posture of abdominal compression; Body movement during measurement; When room temperature changes rapidly; When the measuring site or environment changes frequently; Long time continuous measurement.

3, HOW TO EVALUATE YOUR BLOOD PRESSURE

The World Health Organization (WHO) has created the following guide for assessing high blood pressure (without regard to age or gender). It is important to note that various factors (e.g. diabetes, obesity, smoking, etc.) also need to be considered. Consult with your physician for an accurate assessment and diagnosis of your health condition. This chart is not intended to provide a basis for any type of diagnosis or emergency assessment; this chart only depicts different classifications of blood pressure. Consult your physician for an interpretation and diagnosis based on your personal blood pressure results.

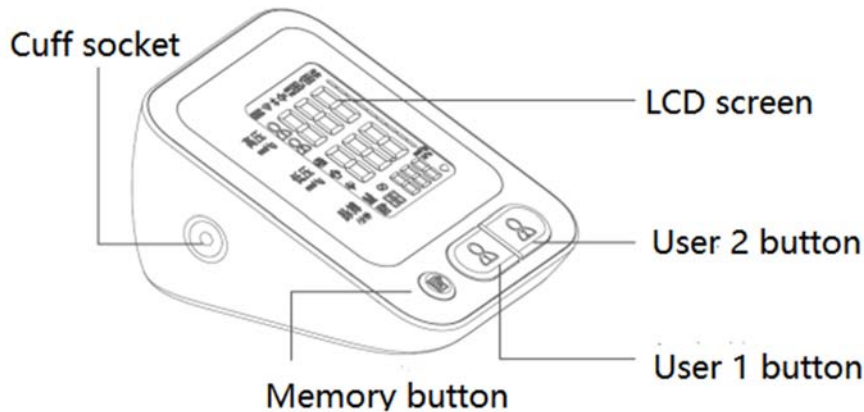
BLOOD PRESSURE CLASSIFICATION CHART	Systolic BP mmHg	Diastolic BP mmHg	COLOR INDICATOR
Optimal	< 120	< 80	Green
Normal	120 - 129	80 - 84	Green
High-Normal	130 - 139	85 - 89	Yellow
Grade 1 Hypertension	140 - 159	90 - 99	Yellow
Grade 2 Hypertension	160 - 179	100 - 109	Red
Grade 3 Hypertension	> 180	> 100	Red

WHO/ISH Definitions and Classifications of Blood Pressure Levels Source: Chalmers J et al. WHO-ISH Hypertension Guidelines Committee. 1999 World Health Organization - International Society of Hypertension

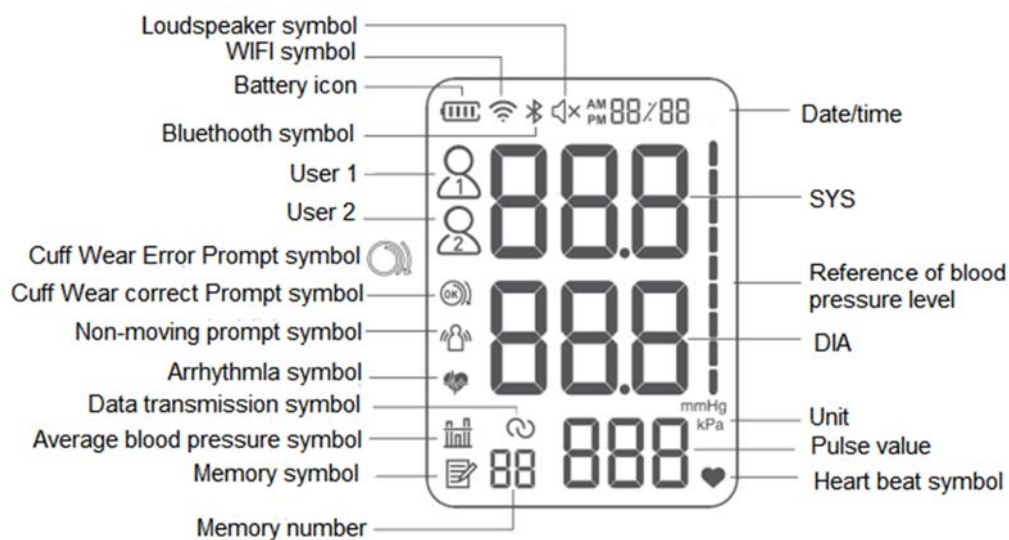
4, Product introduction

4.1, Product structure

The product is mainly consists of main unit and cuff.



4.2 LCD display

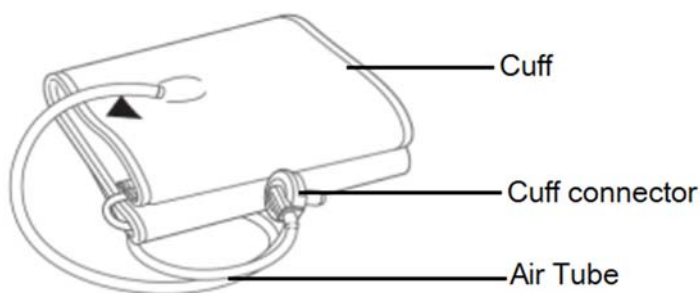


※The display will be different for different models, as shown in the table below.

Display	Backlight	Applicable Model
VA LCD	Yes	SP10A
TN LCD	Yes	SP10B
TN LCD	No	SP10C

4.3 Cuff

This cuff is available in 22-32 cm; it contains air tube and cuff connector. The cuff is a consumable item. If necessary, please purchased from manufacturer separately.



Note:

Do not use cuffs and other parts that are not specified by the manufacturer. Otherwise it may affect the measurement results

4.4 Specifications

Product Name	Upper Arm Blood pressure Monitor
Models	SP10A
Measurement Principle	Oscillometry
Measurement site	Upper arm
Cuff Size	22cm~32cm
Measurement Range	Systolic Blood Pressure: 50~270 mmHg (6.7~36.0) kPa Diastolic Blood Pressure: 30~220 mmHg (4.0~29.3) kPa Pulse: 40~180 beats/minute
Accuracy	Pressure: $\pm 3\text{mmHg}$ ($\pm 0.4\text{kPa}$) Pulse: $\pm 5\%$
Resolution ratio	1mmHg/0.133kPa
Pressure displayed range	0-290mmHg(0-38.6kPa)
Size of main unit	123mm*155mm*82.5mm
Weight	SP10A SP10B about 395g (include cuff) SP10C about 375g (include cuff)
Power source	Charge input: DC 5V,1A ; Power supply: DC 3.7V / 2000mAh Rechargeable Li-ion battery
Service Life	5 years (use 6 times one day)
Memory Capacity	2 x 99 sets of data including date and time
Automatic shutdown	60s no operation

Inflation	Automatic inflation by internal pump
Deflation	Automatic speed deflation system controlled by internal electromagnetic valve.
Waterproof	IP22
Degree of protection against electric shock	Type BF applied part
Type of protection against electric shock	Internally power equipment
Mode of operation	Continuous operation
Software version	V1.0
Working Environment	Temperature: 5°C ~ 40°C Humidity: 15~85%RH Atmospheric Pressure:70 kPa to 106 kPa
Storage Environment	Temperature: -40°C ~ +55°C Humidity: 10~93%RH Atmospheric Pressure:70 kPa to 106 kPa

4.5 Wireless transmission function introduction

These device have wireless transmission function through bluetooth and wifi:

1. After the measurement is completed, first bind the device via Bluetooth.
2. After the device is bound, it will be bound to WiFi via Bluetooth.
3. After the measurement is completed, the device will check whether WiFi is bound. If WiFi is bound, the data will be automatically uploaded to the corresponding user account of the cloud server. If the user clicks the Sync Now button, the data will be downloaded from the cloud server. Bind, it will check whether the Bluetooth is bound
4. If WiFi is not bound and Bluetooth is bound, the user can click the sync button in the app to synchronize the data after the measurement is completed. After the data is synchronized, it will be uploaded to the account corresponding to the server via the mobile phone.



Warning: For safety use of the device, please update the security software of smartphone timely.

The specification of wireless transmission

Bluetooth	5.0
Valid Transmission	Up to 10 meters
Receiver	Bluetooth 4.0 enabled smart phones running android 4 and above system version and iPhone 4s and above
Bluetooth frequency	2402~2480MHZ
Bluetooth frequency characteristic	2.4GHZ

Bluetooth Modulation Type	GFSK
---------------------------	------

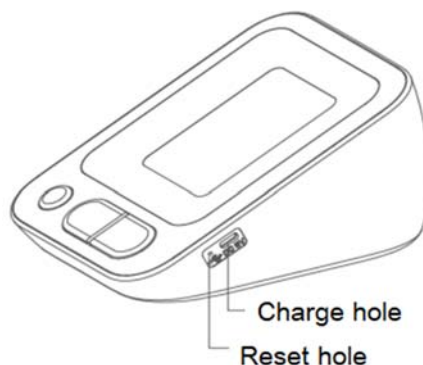
Transmission type	Wi-Fi
Valid Transmission (Distance between Wi-Fi APP and blood pressure monitor)	Up to 10 meters
Wi-Fi APP running environment	Enable smart devices running android 4 and above system version and iPhone 4s and above
WIFI frequency	2412~2462MHZ
WIFI frequency characteristic	2.4GHZ
WIFI Modulation Type	802.11b: DSSS (CCK, DQPSK, DBPSK);802.11g/n: OFDM (64QAM, 16QAM, QPSK, BPSK)

Remark: The use of the monitor will not be affected if the wireless transmission function is not used.

5 Charging battery

When the battery symbol  is displayed and flashed on the LCD, the LCD will display “Lo”, please charge the device in time. Charge the battery as below:

Connect the USB line to the power adapter, then insert another end of USB line to the Charge hole of device, then insert Power adapter plug into supply power socket.



The device will take approximately 3 hours to fully charge , during charging , the battery symbol will flash to hint.

After the battery is fully charged, the LCD will display  symbol without flashing;

Unplug the USB line from the charge hole after charging is completed , remove the power adapter from supply power socket.

Remark:

Normally ,the battery can be recharged for about 300 times. Four times measurement a day, the battery can generally be used for 60 days after being fully charged.

Note:

When the button fails or the screen is not displayed, please insert a needle with a diameter less than 1.5mm into the reset hole and press it for 2 seconds to reset.



In case of the following, please charge immediately

- The icon " of low battery indicator flashes, and the display shows "Lo".
- The LCD does not display after pressing the button



Warning

- We don't provide power adapter. Please purchase DC 5V1A power adapter which has passed IEC 60601-1 test. Do not use damaged power adapter, otherwise the monitor may be damaged or inaccuracy.
- After fully charging the battery, if the working time of battery is shorter than before and you want to replace, don't try to replace the rechargeable battery by yourself. Please the manufacturer for replacement. Self-disassembly and replacement the battery may cause damage to the monitor and battery.
- Whenever the device is not used frequently, charge the battery once a month.

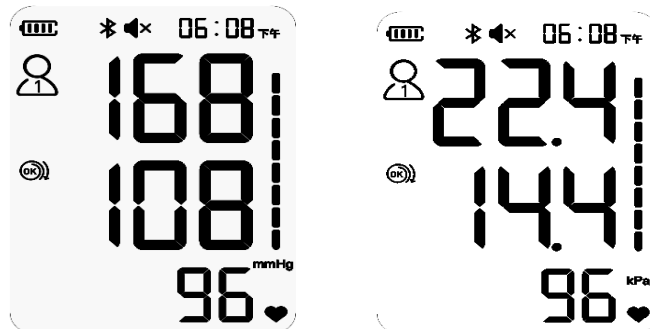
6.Directions for use

6.1 System setting

1) Unit setting

Keeping press the user 1 button " about 3s, the LCD will display flashed "mmHg" or "Kpa", press the memory button " to switch the unit, then press the user 2 button " to confirm the selection.

※In the unit setting state, press the user1 button "' can cancel the setting and power off the device.



2) Volume setting

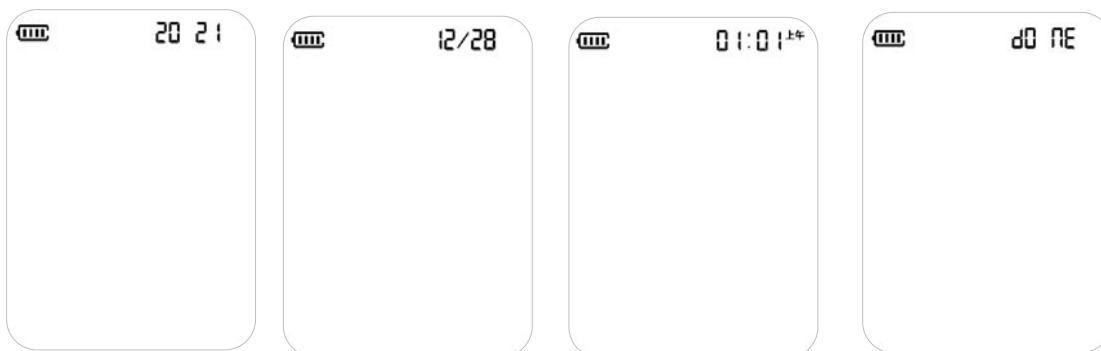
Keeping press the user 2 button " about 3s, the LCD will enter volume setting mode and display flashed "Voice level", press the memory button " to adjust the volume, then press the user 2 button " to confirm the selection.

※In the volume setting state, press the user1 button "' can cancel the setting and power off the device.

3) Date/time setting

Keeping press the memory button " about 3s, the LCD will enter date/time setting mode.

- 1) When the "Year" is flashing on the LCD, press the memory button " to increase the cycle of the year, press the user 2 button " to confirm the setting, and enter the "Month" setting.
- 2) When the "Month" is flashing on the LCD, press the memory button " to increase the cycle of the month, press the user 2 button " to confirm the setting, and enter the "Date" setting.
- 3) When the "Date" is flashing on the LCD, press the memory button " to increase the cycle of the date, press the user 2 button " to confirm the setting, and enter the "Hour" setting.
- 4) When the "Hour" is flashing on the LCD, press the memory button " to increase the cycle of the hour, press the user 2 button " to confirm the setting, and enter the "Minute" setting.
- 5) When the "Minute" is flashing on the LCD, press the memory button " to increase the cycle of the minute, press the user 2 button " to confirm and finish the setting.
- 6) After setting, the LCD will display "done" and enter sleep mode 2 seconds later.
- 7) In the date/time setting state, press the user1 button " can cancel the setting and power off the device.



6.2 Measurement

Notice:

Don't smoke or drink pungent drinks such as coffee or wine, or do strenuous exercise for 30 minutes before measure your blood pressure.

At least rest for 15 minutes in a stable environment before measurement.

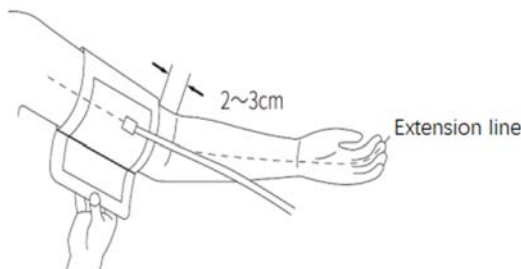
You must repeat the measurement at least two times for accuracy, and take at least 2 minutes' rest or more time before next measurement.

Please sit down and don't move your body during the measurement, if you are lying down during the measurement, please take note.

6.2.1 Wrap the cuff

- 1) Insert the cuff connector into the cuff socket.
- 2) Remove the thicker clothing on the measured arm, expose the upper arm or leave only the thinner clothing.

- 3) Put upper left arm through the cuff.
- 4) Ensure the position of air mouth is at the inner side of the arm. and the extension line of the air hose should be aligned with the middle finger. Place the arm cuff 2~3cm above the elbow.
- 5) Pull one end of the cuff outward and tighten, fix the position of the cuff .



Caution

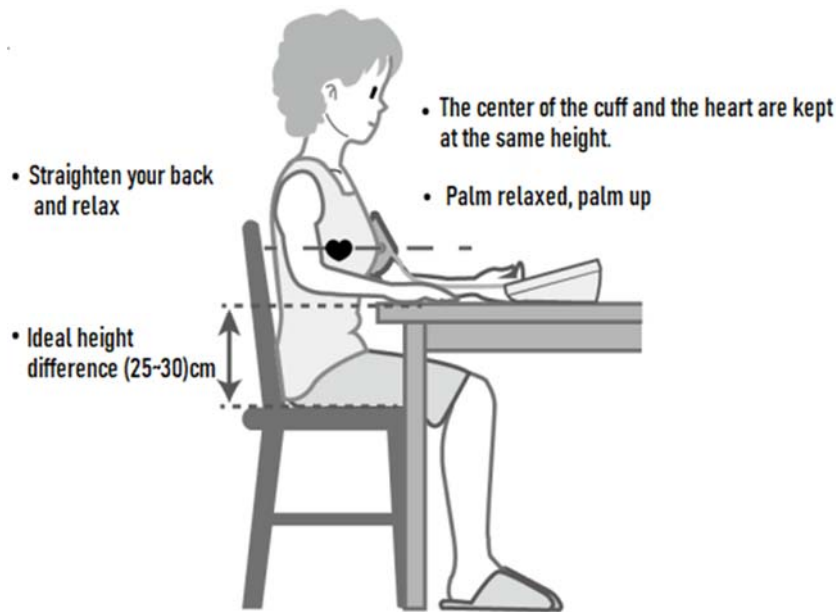
The cuff should be twined comfortably to the upper arm, there should be no gap between the arm and the cuff to prevent too tight or loose, it is advisable to reach into two fingers.

Do not start pressing before the cuff is wrapped around the arm.

This monitor has the function of automatically detecting whether the cuff is worn correctly. If the LCD shows “OK”, it means that it is worn correctly, and you can continue to measure; If “X” is displayed, it means incorrect wearing. Please wear it again according to the above requirements.

6.2.2 Correct measuring position

- 1) Please sit in a room with suitable temperature for measurement. Your body should be relaxed as much as possible and your sitting posture should be natural. You shall sit in a chair with your legs uncrossed and your feet flat on the floor.
- 2) Please keep the middle of cuff at the level of the right atrium of the heart as shown in the figure below, If the monitor is too high above your heart, your blood pressure will be artificially low. If the monitor is too low below your heart, your blood pressure will be artificially high.
- 3) Relax your arm and hand. With the palm of the hand facing up, do not bend your arm back, clench your fist, or bend your arm forward.



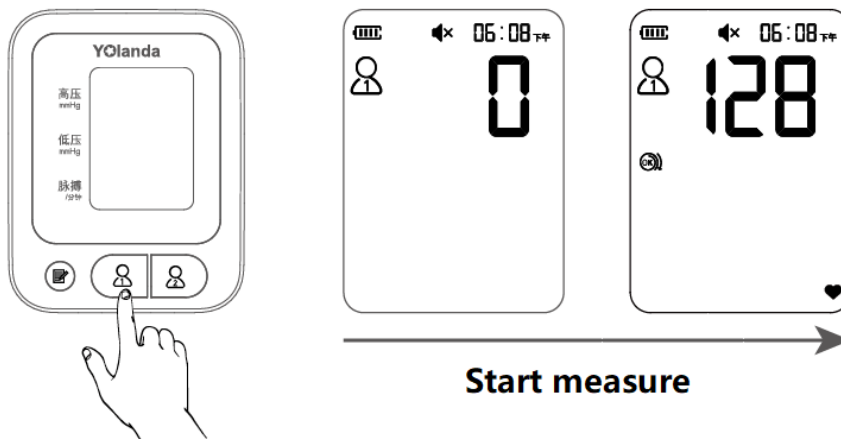
Caution:

- Do not take the measurement immediately after eating, drinking, smoking, exercising or showering, and wait at least 30 minutes before starting the measurement.
- Please take a rest at least 15 minutes before each measurement, and at least 2 minutes between continuous measurements.

6.2.3 Blood pressure measurement procedure

- 1) After the cuff has been appropriately positioned, press the User1 “

LCD will display “



Hint: Determine your blood pressure based on each measurement and the blood pressure table, and consult your doctor.

- 3) Take off the cuff from your arm and turn off the device by press the User1  or User2  button. (If there is no operation for 60 seconds, the device will be automatically off.)

Emergency stop!

Stop the measurement in emergency condition:

In the process of measurement, if the subject feels uncomfortable or needs to interrupt the measurement due to some other reasons, please press the user1/2 button, the machine will stop the measurement immediately and quickly discharge the air in the cuff to reduce the pressure. If the user1/2 button fails, please unfasten the cuff and stop the measurement.

6.3 Prompt function of irregular heartbeat

This monitor can detect the situation of irregular heartbeat. In the measuring process, if the appearance of this "



" symbol signifies that an irregular heartbeat was detected, it means that the result may deviate from your normal basal blood pressure. This indicator is only a caution, it is important that you be relaxed, remain still and do not talk during measurements. Please repeat the measurement.

An irregular heartbeat rhythm is defined as a rhythm that is 25% less or 25% more than the average rhythm detected while your monitor is measuring blood pressure. 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 you to consult with and follow directions of your physician.

Note:

If you have severe arrhythmia, it is very likely that you will not be able to measure the blood pressure.

6.4 Voice broadcast

Broadcast state	Broadcast content
Start measure	Start measuring now
Finish measurement	The result of this measurement is XX, systolic blood pressure is XX, diastolic blood pressure is XX, and pulse is XX beats per minute, I wish you a good health, thank you for using
Measurement failure	The measurement failed, please try to wear the cuff and start a new measurement again
Memory broadcast	Systolic blood pressure was XX, diastolic blood pressure was XX, and pulse was XX beats per minute, I wish you a good health, thank you for using
Low battery	Low battery, Please charging the device soon

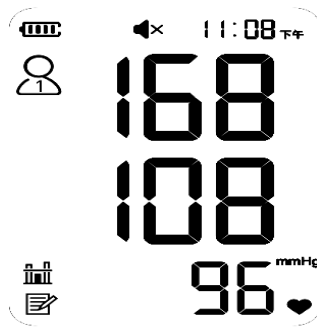
Note: XX is the voice content corresponding to the measured actual value.

6.5 Memory Function

6.5.1 Check the measurement records

- 1) In the shutdown state, press memory button  enter memory mode.

2) Press memory button  again, the LCD display average measurement data as below:



3) Press memory button  again, the LCD display the latest measurement data as below:



4) Every time you press the memory button  briefly, you can look through the next set of measurement data in the order of measuring time from near to far, and you can view Max.99 sets of records of current user.

5) While viewing the historical data of user 1 or user 2, press another user button to switch to display the measurement data of another user.

※ In the state of viewing history data, when viewing the user1 data, press the user1 button again to shut down immediately, it also apply to user 2. If you forget to shut down, the monitor will shut down automatically after 1 minute.

Automatic replacement: For each user group, if the stored measurement results exceed 99 groups, the oldest historical data will be automatically deleted and new measurement data will be recorded.

6.5.2 Memory deletion

Deleting current data: in memory mode, press the "user 1 button" and "user2 button "for 3 seconds at the same time. When the LCD shows "del+ current data number" flashing, press the user2 button to confirm deletion.

※ under deletion of current data state, press user1 button can cancel the deletion and shut down the device.

Deleting all records: under the power off state, press the "user 1 button" and "user2 button "for 3 seconds at the same time. When the LCD shows "dEL ALL" flashing, press the user2 button to confirm deletion.

※ under deletion of all data state, press user1 button can cancel the deletion and shut down the device.

6.6 Wireless transmission function operation

6.6.1 APP Download and Installation

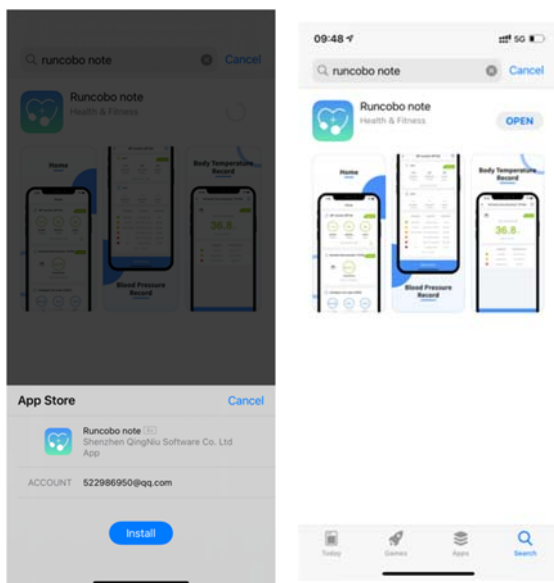
Search "Runcobo note" in the App Store or other App markets to download and install the App.



6.6.2 APP installation

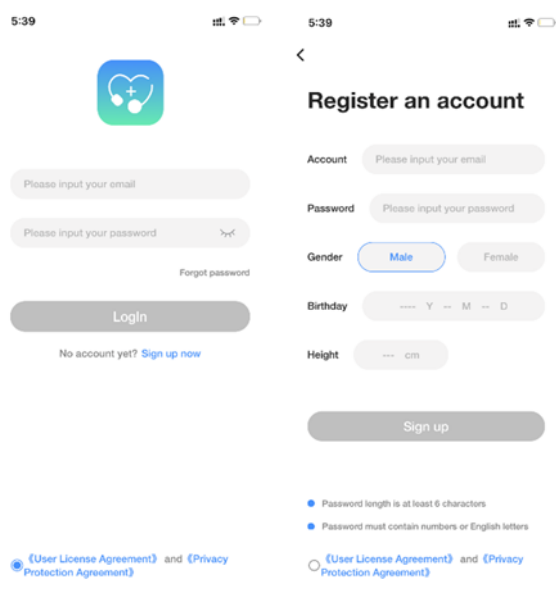
Click "get" to install after verification. After the installation is successful, the "get" icon will change to "open". Click "open" to open the app

X



6.6.3 APP Registration

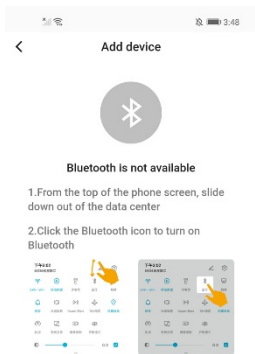
After installed the APP, open it and then complete registration follow the instruction on APP interface.



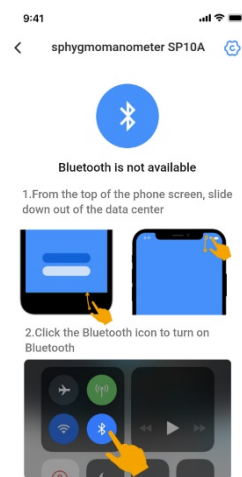
6.6.4 Connect with APP and blood pressure monitor via Bluetooth

1) Turn on the Bluetooth function

Android phone: Turn on the Bluetooth and Position as below Figure:

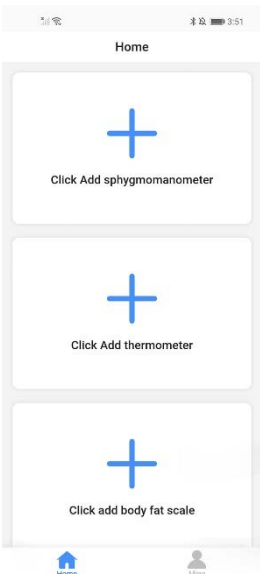


iPhone: Turn on the Bluetooth and limits of authority as below Figure:



2) Binding blood pressure monitor

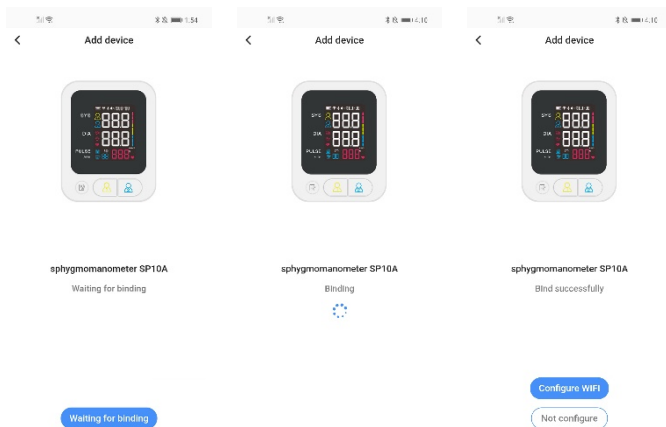
a) Click "Add Blood Pressure Monitor" and wait for the monitor to connect with APP as below figure:



b) Turn on the monitor and start measure the blood pressure. When the measurement is finished, the blood pressure value is displayed on the LCD of monitor, and then APP will search the monitor automatically, When the APP search the monitor, click "Binding Now". button as below figure:



c) Don't turn off the blood pressure monitor until the binding completed as below:

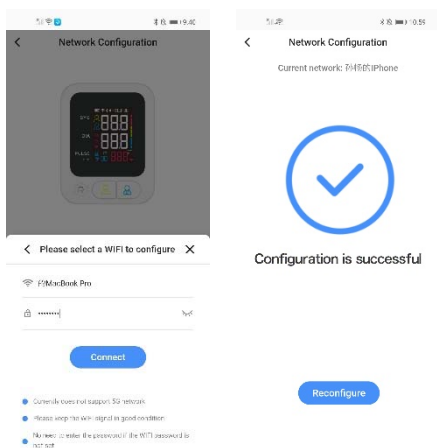


6.6.5 Connect with APP and blood pressure monitor via WiFi

1) Select 2.4GHz WiFi to connect as below figure:

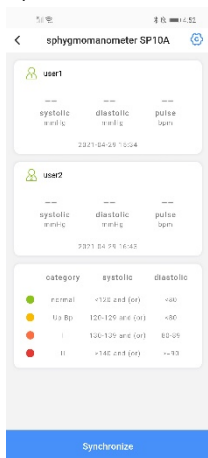


2) Enter the WiFi password and wait for connect completed as below figures:

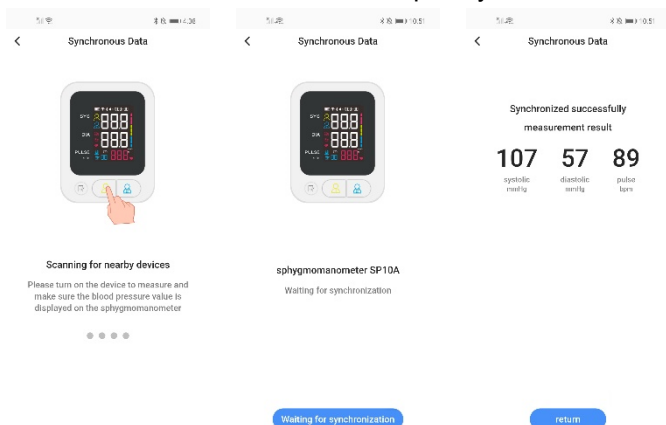


3) Connect with blood pressure monitor

a) Click "Immediate synchronization" and wait for the monitor to connect with APP as below figure:

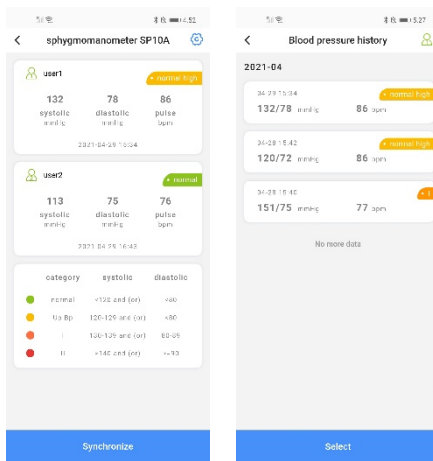


b) Turn on the monitor and start measure the blood pressure. When the measurement is finished, the blood pressure value is displayed on the LCD of monitor, and then APP will search the monitor automatically, When the APP connect with the monitor completely, the measurement data will synchronize as below figure:

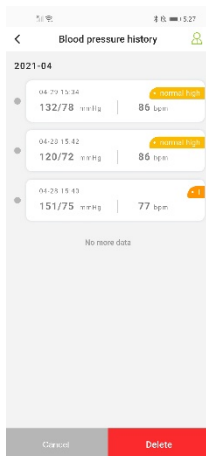


6.6.6 Check the history data

1) Click on User 1 or User 2 display on app to check the user's historical measurement data as below:



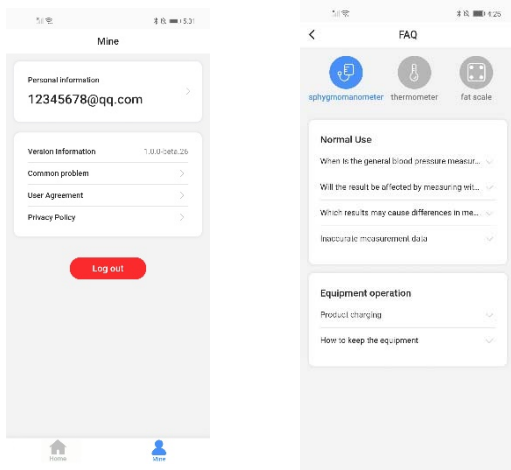
2) Click [Select] to delete the historical data follow below figure:



6.6.7 FAQ

Click the "FAQ" on APP interface to see the help for frequently asked questions as below figures:

XXX

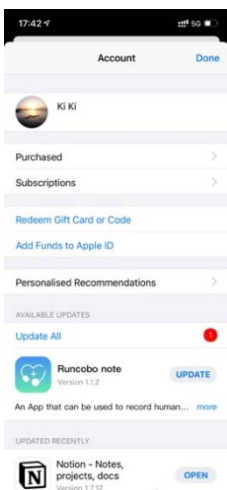


6.6.8 APP update

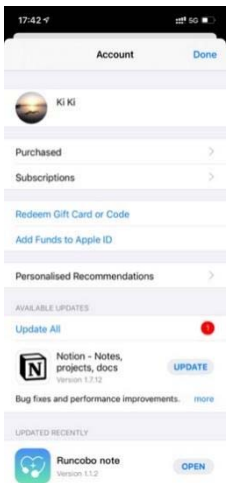
1) Click on the avatar on the homepage to enter the app update page



2) Click "update" to update



3) When "update" changes to "open", it means the update is complete, click "open" to open the app



7. Clean the monitor and cuff

Clean the monitor and wrist cuff:

1) Make sure the monitor is off prior to cleaning.

- 2) Using a spray bottle, moisten a soft cloth towel with the neutral soap until it is fully saturated. Squeeze any excess water from the cloth to avoid any dripping of the monitor and wrist cuff.
- 3) Wipe all surfaces of the monitor and wrist cuff thoroughly, making sure to clean the inside and outside of the cuff.
- 4) Using a soft dry cloth, gently wipe away any excess moisture on the monitor and wrist cuff. Naturally dry the monitor and cuff.

Note:

Do not use any abrasive or volatile cleaners.

Do not wash or immerse your monitor and wrist cuff in water.

Do not use gasoline, thinners or similar solvents to clean your monitor and wrist cuff.

8. Calibration and maintenance

Calibration: the accuracy of this product has been strictly tested. It is recommended to check and calibrate this product every one year to ensure the normal function and accurate measurement of this product. Specific calibration method please call the customer service hotline.

Maintenance: in order to ensure the accuracy of measurement, please do not disassemble or modify the Upper Arm Blood Pressure Monitor without permission. If you find quality problems, please call the customer service hotline.

9. Error indicators and troubleshooting

9.1 Error indicators

Err No.	Possible Cause	Handling method
Err1	Device is not calibrated	Please contact customer service for processing
Err2	Cuff off/over-action	Please check cuff condition/keep quiet during measurement
Err3	Fail to measure SYS	Please maintain the correct measuring posture and re-measure
Err4	Fail to measure DIA	
Err5	No blood pressure and pulsation was detected	
Err6	Measurement timeout	
Err7	Too much pressure	Do not touch the cuff during measurement. Avoid bending the cuff air hose
Err8	Air leaks during pressurization	Please check the integrity of the cuff and seal ring
Err9	The cuff is not connected	Please attach the equipment to the cuff; or The bleeder valve is damaged, please contact customer service for handling
Err10	WiFi fail to upload	Do not stay away from your router or check for network problems

9.2 Troubleshooting

The following table is the common faults that may occur in the process of use and their troubleshooting methods.

Problem	Solution
Button was pressed, but the monitor has no response	Please charge the device. If there is no charging indication, Insert the reset hole with a needle object less than 1.5mm in diameter to reset the device.
The device frequently fails to measure the blood pressure values, or the values measured are too low or too high	1. check the position of the cuff, and re-wrap the cuff at the correct position 2. Keep quiet and relaxed and re-measure the blood-pressure
Blood pressure measured differs from those values measured by the doctor. Every measurement produces a different value although the instrument functions normally and the values displayed are normal.	1. attempt to carry out the measurements regularly at the same time of each day, since the blood-pressure changes during the course of the day 2. record the daily development of the values and consult your doctor.
The air pump works, but the air pressure does not rise.	Check if the arm cuff connection is good and there is no air leak

If the above situation cannot be excluded in use, or any failure other than the above occurs, please contact customer service!

10.Storage

Storage environment: store in accordance with the storage environment conditions specified in this manual, avoid moisture, high temperature, falling, dust, sun exposure, vibration, chemicals or corrosive gas, etc.

11 . Standard list

SHENZHEN YOLANDA TECHNOLOGY CO., LTD. declares that the Upper arm blood pressure monitor complies with following regulations and normative documents/standards:

2017/745 Medical device regulation	
COUNCIL DIRECTIVE 2014/53/EU of 16 April 2014 relating radio equipment (RED)	
EN ISO 15233-1	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1 General requirements
EN 1041	Information supplied by the manufacturer with medical devices
EN 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6	Medical electrical equipment – Part1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 60601-1-11	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical

	systems used in home healthcare environment
IEC 80601-2-30	Medical Electrical Equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 81060-2	Non-Invasive Sphygmomanometers - Part 2: Clinical Validation of Automated Measurement Type
EN 62304	Medical device software - Software life-cycle processes
EN 62366	Medical devices – Application of usability engineering to medical devices
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

12 . Disposal



Dispose of the device in accordance with the regulations applicable at the place of operation. Dispose of at public collection point in the EU countries – 2002/96/EC WEEE Directive. If you have any queries, please refer to the local authorities responsible for waste disposal.

NOTES:

- Handling of battery and wastes method, please act according to the native law to proceed to handle.



To protect the environment, dispose of empty battery at your retail store or at appropriate collection sites according to national or local regulations.

13 . NORMALIZED SYMBOLS

Symbol	Explanation
	Please do not disassemble or repair or modify the Blood pressure Monitor and its accessories
	Manufacturer
	Follow operating instructions
IP22	The first number 2: Protected against solid foreign objects of 12.5 mm Φ and greater. The second number 2: Protected against vertically falling water drops when enclosure tilted up to 15° .
	BF type applied part
	Disposal in accordance with Directive 2002/96/EC (WEEE)
	Complies with the European Medical Device Regulation (2017/745. Notified Body is SGS.

	Authorized representative in the European Community.
	Batch code
SN	Serial number
	Date of manufacture
	Keep dry
	Upward
	Fragile, handle with care
	Pile Limit 6 layers

14. Package list

Only use original accessories. Check that the contents of the delivery are complete.

Quantity	Parts	Part No.
1pc	Main unit	SP10A
1pc	USB line	22-23
1pc	Cuff (with Air hose)	USB100032W
1pc	User Manual	/

15. 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:

- Change in the reading for the measurement of the cuff pressure at any point of the nominal measurement range shall not be greater than 2mmHg (0.3kpa) during and after exposure to non-transient phenomena and after exposure to transient phenomena.

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
USB line	1m	No

Guidance and manufacture's declaration – electromagnetic emission		
The upper arm blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer of the user of the upper arm 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 upper arm blood pressure monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference

		in nearby electronic equipment.
Conducted RF emissions CISPR 11	Group 1 Class B	The <i>monitor</i> 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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations and flicker emissions IEC 61000-3-3	Applicable	

Guidance and manufacture's declaration – electromagnetic immunity			
The upper arm blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the upper arm 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 (Professional healthcare facility environment); 10V/m (Home healthcare environment), 80MHz – 2.7GHz 80% AM at 1kHz	10V/m (Home healthcare environment) 80MHz – 2.7GHz 80% AM at 1kHz	
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;	Mains power quality should be that of a HOME HEALTHCARE ENVIRONMENT or a Professional healthcare facility environment.

Surges IEC 61000-4-5	$\pm 0.5\text{kV}$, $\pm 1\text{kV}$ lines to lines; $\pm 0.5\text{kV}$, $\pm 1\text{kV}$, $\pm 2\text{kV}$ lines to earth	$\pm 0.5\text{kV}$, $\pm 1\text{kV}$ lines to lines;	Mains power quality should be that of a HOME HEALTHCARE ENVIRONMENT or a 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 (Professional healthcare facility environment), 6V in ISM and amateur radio bands between 0.15MHz and 80MHz (Home healthcare environment) 80% AM at 1kHz	Applicable	
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 or a 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	Mains power quality should be that of a HOME HEALTHCARE ENVIRONMENT or a 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 upper arm blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the upper arm 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	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 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 ^{b)} 18 Hz	2	0,3	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	2	0,3	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	2	0,3	28

5 240	5100 – 5800	WLAN 802.11	Pulse modulation ^{b)}	0,2	0,3	9
5 500		a/n	217 Hz			
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, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Recommended separation distances between portable and mobile RF communication equipment and upper arm blood pressure monitor			
The upper arm blood pressure monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment			
Rated maximum output power of transmitter/ W.	Separation distance according to frequency of transmitter/m		
	150kHz ~80MHz $d = 1.2\sqrt{P}$	80MHz ~ 800MHz $d = 1.2\sqrt{P}$	800MHz~2.5GHz $d = 2.3\sqrt{P}$
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 meters (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 80MHz and 800MHz, 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.			

16.After-sales service

Within 12 months from the date of product purchase (subject to the official purchase invoice), under normal use, the device and function of the machine itself have problems and can not be used normally. We will provide maintenance or replacement free of charge. Please keep the warranty card in the package as a maintenance certificate.

Free maintenance service is not provided in the following cases:

- The product is out of warranty. Product failure or damage caused by unauthorized disassembly, maintenance, negligence, abuse, liquid intake, accident or modification.
- Product failure or damage caused by accident or human factors (such as strong throwing, beating, scratching, etc.).
- Product failure or damage caused by force majeure such as natural disasters (such as earthquake, fire, etc.).

When you need warranty service, please show your warranty card.

- If you can't show your warranty card or prove that the product is within the warranty period, our company

- has the right not to provide free maintenance service.
- For products that exceed the free warranty period and are not covered by the free regulations, spare parts and maintenance fees shall be charged.

17.FCC compliance statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

Warranty Card

Name		Purchasing date	
TEL		Seller Name	
E-mail		Product model	
Fault phenomenon	Failure cause	Repair content	
The date of repair :		Signature of maintenance personnel :	



Manufacturer: SHENZHEN YOLANDA TECHNOLOGY CO., LTD.

Address: Room 201,Jinfulai Building, No.49-1, Dabao Road,Dalang Area,Xinan Street,Baoan,

Shenzhen, China

Tel: 86-755-21635022

Customer service hotline : 86-400-998-2913 (service time: 9:00 to 21:00 of working day)

Email: service@yolanda.hk

Website: www.yolanda.hk

Document No.: 20210501V1.0

User manual Edition:V1.0

Printed on: Feb. 2021