

Pump work, but the pressure does not rise	Whether Wrist cuff is poor connections , there is leakage	Ask for repair
	Whether Wrist cuff damaged due to long years	Please buy a new one
Wrist Cuff leak in a short time	Whether the Wrist cuff too loose	Please wrap the Wrist cuff correctly
Even if you press the ON / OFF button , can not enter the measurement		Please re-power, measured again
During measurement suddenly power off	When not use for a long time, the temperature variation may make the battery power exhausted	Change a new battery
The machine is in good working condition, but the results of each measurement is different	Mental state and the measured time will cause measurement values changes in blood pressure	Before measurement , Please take a deep breath and keep in a quiet state Note: Blood pressure is dynamic, so must be some difference between the measured value every time
The measured values of arm and wrist is different		Please refer to the "relevant Wrist type Blood Pressure Monitor"

24

9 Manufacturer’s Declaration of the EUT

Statement:

- The Wrist Type Blood Pressure Monitor or user should use the product in the electromagnetic environment specified in the following table, otherwise it may cause abnormal operation of the product.
- The internal structure of the Wrist Type Blood Pressure Monitor adds magnetic rings, magnetic beads, and conductive cloth to spray conductive paint to avoid electromagnetic interference, so as to prevent adverse events to patients and operators due to electromagnetic interference.
- Wrist Type Blood Pressure Monitor is a table-top equipment, it suitable for medical unit and home use.
- Warning: Use of this Wrist Type Blood Pressure Monitor adjacent to or stacked with other equipment should be avoided because it could result in improper observed to verify that they are operating normally.
- Warning： Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in impropor operation.
- Warning： Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Wrist Type Blood Pressure Monitor, including cables specified by the

30

NOTE: If necessary to achieve the immunity test level, the distance between the transmitting antenna and the equipment or mc 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.	
--	--

10 Maintenance and storage

10.1Maintenance methods

- Keep the blood pressure clean frequently
- Using a soft dry cloth towel clean this blood pressure monitor, if it is very filthy you can wet the towel with water or neutral detergent, wring out it and wipe the monitor.
- Don't clean the blood pressure monitor with naphtha, thinner or gasoline etc.
- Don't wet the wrist cuff or attempt to clean the wrist cuff with water.

Attention

Please prevent water or other liquid seep into the blood pressure monitor.

Suggestion

Don't clean the host and wrist cuff with naphtha, thinner or gasoline etc. Don't wet the wrist cuff or attempt to clean the wrist cuff with water.

36

Working condition	Temperature	+5℃～40℃	If stored or used outside the specified temperature and humidity range, blood pressure monitor will not work properly.
	Humidity	15%RH～80%RH	
	Atmospheric	86kPa～105kPa	
Transporting and storing condition	Temperature	-20℃～55℃	Avoiding strong impact,direct impact, exposure or rain when transporting. Packed blood p ressure monitor a should be stored in the condition met the humidity and atmospheric requirements, and non-corrosive gases and ventilated room.
	Humidity	15%RH～95%RH	
		50kPa-	
	Atmospheric	105kPa	
Security Type	Internal power supply, BF type application equipment		
Service life	5 years		
Wrist cuff specification	13.5cm-19.5cm		
Accessories	2 AAA alkaline batteries		
the time required for me equipment to warm from the minimum storage temperature between uses until it is ready for intended use;			About 30min
the time required for me equipment to cool from the maximum storage temperature between uses until it is ready for intended use			About 30min
the time from switching "on" until the me equipment is ready for normal use, when it exceeds 15 s			About 10 seconds

42

The measured values of blood pressure is different with doctors measured, even serious small	Record results of your daily blood pressure test, using which to consult with a doctor PS: Frequent consultation with a doctor may cause Psychological stress, which will let your blood pressure test value higher than value under a relax state
Other anomalies	Please press the start button and check again or change a new battery, if still can't measure pleasure connect us.

7 Memory function

7.1 Memory Recall

This blood pressure storing 99 set memory value, each measurement it will automatically stored. When it stored 99 set memory value, the old value will be covered by the new one. It can show the latest 3 times average value.

Attention

In order to make a note of measurement correctly, before measurement, please make sure set the right user and time. Under one user, it has stored 99 set data, when you save the 100th set data, the earliest one date will be deleted.

7.1.1 Read Average Value

Short press the MEMORY key it will show the latest 3 times average value. It will appear “AVG” on the screen;

25

manufacturer. Otherwise, degradation of the performance of this Wrist Type Blood Pressure Monitor could result.

Guidance and manufacturer’s declaration – electromagnetic emission – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer’s declaration – electromagnetic emission		
1	Guidance and manufacturer’s declaration – electromagnetic emission	
2	The wrist type blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of wrist type blood pressure monitor should assure that it is used in such an environment.	
Emissions test	Compliance	
3		
4	RF emissions CISPR 11	Group 1
5	RF emissions CISPR 11	Class B
6	Harmonic emissions IEC 61000-3-2	N/A
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A

31

10.2 Storage Methods

Do not place the unit in the following places:

- Easy splashing.
- Direct sunlight, high temperatures, humidity, dust, full of corrosive gas places.
- Some slant, vibrative, appulsive place .
- Some place storing chemicals or corrosive gas.

Attention

Please Storage after taking out the battery if not use the unit long time. (more than three months)

- ③ Do not attempt to replace the parts without authorization.
- ③ Do not disassemble and repair this blood pressure monitor.

- If you do not comply with all notes and the proper usage of the monitor, our company does not assume responsibility for the quality.

10.3 Notes

- Warning: If the performance is inconsistent with the description or changes, stop using immediately and contact the manufacturer.
- Warning: Do not use this product if you are allergic to ABS and other materials.
- Direct use in the environment of electromagnetic interference shall be avoided to prevent temporary influence on its accuracy.

37

Working condition	Temperature	+5℃～40℃	If stored or used outside the specified temperature and humidity range, blood pressure monitor will not work properly.
	Humidity	15%RH～80%RH	
	Atmospheric	86kPa～105kPa	
Transporting and storing condition	Temperature	-20℃～55℃	Avoiding strong impact,direct impact, exposure or rain when transporting. Packed blood p ressure monitor a should be stored in the condition met the humidity and atmospheric requirements, and non-corrosive gases and ventilated room.
	Humidity	15%RH～95%RH	
		50kPa-	
	Atmospheric	105kPa	
Security Type	Internal power supply, BF type application equipment		
Service life	5 years		
Wrist cuff specification	13.5cm-19.5cm		
Accessories	2 AAA alkaline batteries		
the time required for me equipment to warm from the minimum storage temperature between uses until it is ready for intended use;			About 30min
the time required for me equipment to cool from the maximum storage temperature between uses until it is ready for intended use			About 30min
the time from switching "on" until the me equipment is ready for normal use, when it exceeds 15 s			About 10 seconds

43

--	--

Attention

When the number of memory value less than 3 sets, such as there are 2 sets of memory value , after pressing the memory button it will show the average value of these 2 sets. If there is only 1 set memory value, after pressing the memory button it will show the average value of this 1 set , that is the only 1 set measure value.

7.1.2 Read Memory Record

Press the MEMORY key in average mode, you can read the latest 1 time measurement value,repeat press the MEMORY key to cyclic switch in the previous measurements.

26

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer’s declaration – electromagnetic immunity		
The wrist type blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the wrist type blood pressure monitor should assure that it is used in such an environment.		
Immunity test	EN 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15kV air
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines	< 5 % UT (-95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (-95 % dip in UT) for 5 sec	N/A
IEC 61000-4-11		

32

- The product is suitable for professional use or domestic use.
 - The correct use method is the key to the accuracy of measurement.
- Operators should have certain knowledge of blood pressure. The operating environment shall be in accordance with the instructions.
- Warning： Too frequent measurements can cause injury to the patient due to blood flow interference.
 - Warning： The effect of blood flow interference and resulting harmful injury to the patient caused by continuous CUFF pressure due to connection tubing kinking.
 - The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems.
 - Please place the blood pressure monitor in a place where children, pets, etc. can not be touched, so as to prevent falling, biting and affecting the product performance.
 - Do not use beyond the service life of the product, otherwise the accuracy of the instrument will be affected
 - Warning： Portable RF communications equipment (including peripherals such as antenna cables and external antennas)should be used no closer than 30cm(12 inches) to any part of the blood pressure monitor ,including cables specified by the

II. Blood pressure classification instructions

Table 1 Blood pressure classification instructions

LCD	Diastolic Pressure	Systolic Pressure
Serious	≥110	≥180
Moderate	100～109	160～179
Mild	90～99	140～159
Little higher	85～89	130～139
Normal	80～84	120～129
Most suitable	≤79	≤119

the wrist cuff shall deflate within 30 s to the values indicated in ≤15 mmHg, and any indication of blood pressure shall be cancelled

When the supply mains to the blood pressure monitor is interrupted	≤3mmHg
The laboratory reproducibility of the BLOOD PRESSURE DETERMINATION of the AUTOMATED SPHYGMOMANOMETER	
Overvoltage category classification	N/A

--	--

7.2 Memory Clear

Long press the MEMORY key in the memory mode, all memory values will be deleted.

Warning

This operation deletes all memory values, users need to operate carefully.

8 About Wrist Type Blood Pressure Monitor

Blood pressure wrist and upper arm blood pressure value when disease

27

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	
NOTE UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer’s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer’s declaration – electromagnetic immunity
The wrist type blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the wrist type blood pressure monitor should assure that it is used in such an environment.

Immunity test	EN 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A

33

manufacturer.Otherwise,degradation of the performance of this blood pressure monitor could result.

- The blood pressure monitor cannot be serviced and maintained during use.
- The blood pressure monitor should be avoided in places with poor ventilation and high dust and lint content.Avoid direct sunlight and strong light sources.
- If you need maintenance, please contact the manufacturer
- It contains small parts and should be kept out of reach of children to avoid swallowing.
- This wrist type blood pressure monitor is not suitable for use in the presence of electroscopy.

10.4Waste disposal

- 1.Please follow local laws to dispose of waste scrap.
- 2.Follow local ordinances and recycling instructions regarding to disposal or recycling of the device and device components, including used batteries and packaging box.

III. LCD Error message and the cause of error correspondence table

Table 2 LCD Error message and the cause of error correspondence table

LCD Error message	The cause of error
“E0 1”	Because the arm or body movement, the systolic pressure signal can not be measured, please tie the wrist band and test again.
“E0 2”	Because the arm or body movement, the diastolic pressure signal can not be measured, please tie the wrist band and test again.
“E0 3”	Test results are not normal,please measure again.
“E0 4”	Due to leaks too fast or pulse signal is too weak,please check wrist cuff,and after tied please measure again.

Diabetes and high cholesterol and high blood pressure will accelerate atherosclerosis.It can cause dangerous diseases such as stroke or myocardial infarction, or arterial stenosis or peripheral circulatory disorders when this symptom turns serious. Wrist blood pressure values in these patients with upper measure blood pressure may have a greater difference. [Even healthy people due to inappropriate test conditions, there may be a difference about 20mmHg (2.6kPa), so do not be self-judgment, be sure to accept the doctor's guidance.] In addition, the difference between the wrist and upper arm measured blood pressure values, will much affected due to the physiological state, but the changes of the wrist and upper arm measured blood pressure values are the same.Therefore examining trends of change in blood pressure can be based on the measurement of wrist blood pressure .

Wrist and upper arm blood pressure

Normally, blood pressure measurement is used to measure the brachial artery blood pressure of the upper arm. Because the brachial artery in the wrist is connected with the upper arm, so the measured blood pressure value is very closed to that one of the upper arm, and it can also reflect changes of the arm blood pressure. There is a large difference of blood pressure value between wrist and upper arm of those patients who have circulatory system diseases. Please consult experts and make health management in accordance with the upper arm blood pressure value.

28

Table 9 - Test specifications for enclosure port immunity to RF wireless communications equipment

Test frequency (MHz)	Band ^{b)} (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	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
745			Pulse modulation ^{b)} 18 Hz	2	0,3	28
780						
810						
870	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 217 Hz	2	0,3	28
930						
1 720	1 700-1 990	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	2 400-2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28
5 240						
5 500						
5 785						

34

10.5 Verify manometer pressure accuracy

In the power down state, press and hold

the "START/STOP"+Memory key, and then install the batteries.

Until the LCD screen displays “

release the "Start/STOP" button. At this time, the 100ml volumetric standard and Standard stressors can be connected to the wrist type blood pressure monitor through the sleeve interface of the wrist type blood pressure monitor, and 300mmHg pressure can be applied to the effective display range of the wrist type blood pressure monitor, and then press the memory key to correct the wrist type blood pressure monitor display 299mmHg .Calibration can be completed.

Advice

- It is recommended to calibrate the wrist type blood pressure monitor once a year, by the manufacturer.

Warning

Users please do not calibrate by themselves.

29

Blood pressure difference between wrist and upper arm

Normally, the measured blood pressure value will appear deviation between wrist and upper arm of a healthy person in a quiet state. [The difference is within ± 10mmHg (± 1.3kPa)]. However, if measured immediately after exercise or bathing, the change of the difference in blood pressure between wrist and upper arm is large due to large changes in blood circulation.

Correct the measurement position

When the height position of the wrist and the heart is not the same, due to the weight of blood, the blood pressure value will change. When the wrist is positioned higher than the heart, the measured blood pressure value is low; when the wrist position is lower than the heart, the measured value will be high [each 10cm height difference, about 8mmHg (1kPa)] . But because blood pressure measuring are closely related to be posture, so it does not necessarily change in accordance with this value. Be sure to consult the correct measurement posture (see section6.1).

Daily life and wrist blood pressure

Usually around diet, the upper arm and wrist blood pressure does not have a big difference. When bath in the high temperature water, due to the heated skin caused blood vessels shrinkage, the blood pressure rises. But if bathing in warm water, it will expand peripheral vascular, decreased blood pressure, this time, the wrist blood pressure will decreased bigger than the arm blood pressure.

35

Appendx I. Product Specifications

ation b) modulation b) + 5 kHz ion	Maximum power (W)	Distance (m)	Immunity TEST LEVEL (V/m)
modulation b) z	1,8	0,3	27
modulation b) z	2	0,3	28
modulation b) z	0,2	0,3	9
modulation b) z	2	0,3	28
modulation b) z	2	0,3	28
modulation b) z	2	0,3	28
ation b) z	0,2	0,3	9

35

Appendix

I. Product Specifications

Name	Wrist Type Blood Pressure Monitor	
Display	Segment LCD Display	
Prevent into the liquid level	IP22	
Measurement	Wrist-type	
Measurement range	NIBP (Non Invasive Blood Pressure)	Static pressure measurement range: 0-280 mmHg Dynamic pressure measuring range: Systolic blood pressure : 35-240mmHg Diastolic blood pressure : 15-180mmHg
	PR (40±199 times/min)	40-199 times/min
Accuracy	NIBP (Non Invasive Blood Pressure)	≤±3mmHg(±0.4kPa)
	PR(Pulse rate)	±5%
Electrical parameters	Working Voltage: 3V(AAA×2) Low electrical parameters: 2.4V±0.1V showing low power, <2.2V±0.1V power off Blood pressure test current: < 500mA (without pump and valve working condition) Shutdown current: < 100uA	
	Power	
Dimension	2 AAA alkaline batteries	
	①:73.6*60*80 mm ②:79*62*62 mm ③:73.6*60*80 mm ⑤:79*62*63 mm	
Weight	About 78g/120g (with wristband,without battery)	