Digital Blood Pressure Monitor

MODEL: WBP108-S

Instruction manual

Table of Contents

Introduction

▲ Your new digital 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.

▲ This automatic blood pressure monitor could measure the systolic pressure, diastolic pressure and pulse, the components are included the body, cuff and printed instruction manual. Batteries are optional. This unit is intended for the adult using.

▲ Intelligent inflation will reduce the uncomfortable feeling by incorrect inflation, and shorten the measurement time, prolong the cuff's usage lifetime.

▲ 2x99 sets memory function, each measurement result will be displayed on the screen, and automatically stored.This unit has blood classification index, could easy to check your blood pressure.

Please read the manual carefully before you use the unit, and keep the manual well after using.

Safety Information

■ To assure the correct use of the product, basic safety measures should always be followed including the warning and the caution listed in the instruction manual:

Symbol descriptions

The following symbols may appear in this manual, on the label, on the device, or on it's accessories. Some of the symbols represent standards and compliances associated with the device and its use.

⚠ WARNING: This alert identifies hazards that may cause serious personal injury or death.

⚠ CAUTION: This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

Type BF applied part

Manufacturer SN Specifies serial number

Authorized Representative in the European Community

CE 0123 CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.

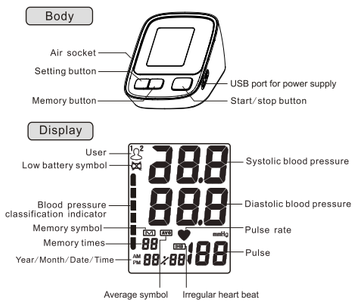
DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.

Keep dry

Follow instructions for use

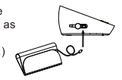
CAUTION: Consult accompanying documents

Product structure



The accessories cuff is M size, for upper-arm circumference 22-36cm use. The cuff is treated as the applied part.

Insert the connector with cuff tube into the hole which is on the left side of the device as picture.（Only provided cuff can be used, can not change to any other branded cuff.）



Safety Information

⚠ For the need to check that operation of the automated sphygmomanometer does not result in prolonged impairment of PATIENT blood circulation;

⚠ Do not mix the old and new batteries.

⚠ Do not use a cellular phone near the unit. It may result in operational failure.

⚠ Please avoid using in high radiant area in order to make your measuring data correctly.

⚠ Do not use the equipment where flammable gas (such as anesthetic gas, oxygen or hydrogen) or flammable liquid (such as alcohol) are present.

⚠ Do not touch the output of AC adapter and the patient simultaneously.

⚠ Do not touch the live end of battery and the patient simultaneously when change the batteries.

⚠ WARNING:
Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact you local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

Classification

1.Internally powered equipment;
2. Type BF applied part;
3.Protection against ingress of water: IPX0;
4.Not category AP / APG equipment;
5.Mode of operation: Continuous operation;

⚠ The user must check that the equipment functions safely and see that it is in proper working condition before being used.

Setting mode

How to set

User setting:

Press the button SET when power off, the screen will display U1 or U2, press the button SET again to change U1 or U2, press the START/STOP button to save the setting.

User setting

Press and hold the button SET when power off until the year show on display.

1. Year setting:

Continue to above step, the screen will display and flash 20XX, the year will increase 1 when press button MEM each time, you could choose from 2017 to 2050. Press button SET when you confirm the year, then it will enter into the month and date setting mode.

Year setting

2. Month and date setting:

Continue to above step, the screen will display month and date, and keep flashing on month, the month will increase 1 when press button MEM each time, you could choose from 1 to 12. Press button SET when you confirm the month, then it will set the date. Same as the month setting, each time you press button MEM, the date will keep changing from 01 to 31. Press button SET when you confirm the date, then it will enter into the time setting mode.

Month setting

Date setting

Proper use of the unit

Measurement

Pre-measurement

- Please keep quiet for 5-10 minutes, and avoid eating, drinking alcohol, smoking, exercising and bathing before taking measurement. All these factors will influence the measurement result.
- Remove any garment that fits closely to your upper arm.
- Always measure on the same arm (normally left).
- Take measurement regularly at the same time of every day, as blood pressure changes even during the day.
- Patient position in normal use:legs uncrossed,feet flat on the floor, back and arm supported.

Common factors of wrong measurement

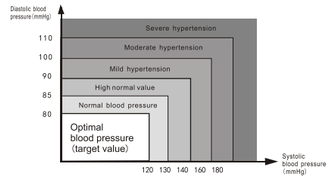
- All efforts by the patient to support their arm can raise blood pressure.
- Make sure you are in a comfortable, relax position and do not activate any of the muscles in the measurement arm during measurement. Use a cushion for support if necessary.
- If the arm artery lies lower or higher than the heart, a false reading will be obtained.

Note:

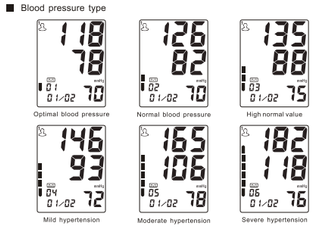
- Only use clinically approved cuffs!
- A loose cuff or a exposed bladder causes false reading.
- With repeated measurements, blood accumulates in the arm which can lead to false reading.
  Consecutive blood pressure measurements should be repeated after 1 minute pause or after the arm has been held up in order to allow the accumulated blood to flow away.

About blood pressure

■ According to the blood pressure classification by the WHO/ISH.
■ SYS lower than 100mmHg (13. 3kPa) is considered as hypotension.



■ Blood pressure type



Warranty information

Statement

■ The intended use：the unit is intended to be used by adults at home or medical center to measure blood pressure and pulse rate from the upper arm.
■ The patient is an intended operator
■ Warning against servicing and maintenance while the me equipment is in use
■ The patient can clean or some other service, e.g. battery changing
■ The unit satisfies the requirements of EN ISO 81060-1:2012 and EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers.
■ Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, manual, electronic, or automated sphygmomanometers.
■ The risk of patient and user can be lowered to acceptable level.

Warranty Information

■ The unit is guaranteed to be free of defects in workmanship and materials under normal use for a period of Two Years from the date listed on the purchase record.
■ For repair under this warranty. Our authorized service agent must be advised of the fault with the period of the warranty. This warranty covers parts and labor only under normal operations. A transportation fee or freight fee that may be incurred will be the owner's responsibility. Any defect resulting from natural causes, eg. flood, hurricane etc, is not within this guarantee. This guaranty does not cover damage incurred by use of the unit not in accordance with the instructions, accidental damage, or being tampered with or serviced by unauthorized service agents.
■ Monitor subjected to misuse, abuse, and neglect of these manual content, non-instructional purposes；unauthorized repair or modifications will be excluded from this warranty.
■ The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems.

⚠ The device requires no calibration.
⚠ The device is not repairable and contains no user serviceable parts.

EMC Declaration

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=
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.

Recommended separation distances between portable and mobile RF communications equipment and the digital blood pressure monitor

The digital 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 digital blood pressure monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the digital blood pressure monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	eparation distance according to frequency of transmitter m		
	150 kHz to 80 MHZ d=3.5	80 MHz to 800 MHZ d=1.2	800 MHz to 2.7 Ghz d=2.3
0,01	/	0.12	0.23
0,1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	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 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.

Safety Information

■ To assure the correct use of the product, basic safety measures should always be followed including the warning and the caution listed in the instruction manual:

Symbol descriptions

The following symbols may appear in this manual, on the label, on the device, or on it's accessories. Some of the symbols represent standards and compliances associated with the device and its use.

⚠ WARNING: This alert identifies hazards that may cause serious personal injury or death.

⚠ CAUTION: This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

Type BF applied part

Manufacturer SN Specifies serial number

Authorized Representative in the European Community

CE 0123 CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.

DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.

Keep dry

Follow instructions for use

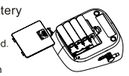
CAUTION: Consult accompanying documents

Battery installation

Battery installation

Remove the battery cover from the battery compartment, insert the battery.

a) Remove the battery cover as picture showed.
b) Insert 4 AA powerful batteries into the compartment and ensure each battery is in the proper direction.



Low battery and replacement

When power on, the low battery symbol will display once the unit start to work. and you must replace with new batteries, otherwise the unit can't work.

Battery type and replacement

Please use 4pcs AA identical 1. 5V alkaline batteries.
Do not use the batteries beyond their expiry date.
Please remove the batteries if you do not need to use for long time.

⚠ WARNING:
Dispose of the battery in accordance with all federal, state and local laws.
To avoid fire and explosion hazard, do not burn or incinerate the battery.

USB power supply

This device can use USB as power supply when you don't use batteries. Please insert the USB cable as the picture showed. The optional AC adapter should comply with the requirement of IEC60601-1:2005, the output is DC 5V, 500mA. Please remove all the batteries before using the AC adapter.

Setting mode

3. Time setting:
Continue to above step, the screen will display hour and minute, and keep flashing on the digits of hour, the hour will increase 1 when press button MEM each time, you could choose from 0 to 23. Press button SET when you confirm the hour, then the digits of minute start to flash. same as the hour setting, each time you press button MEM the minute will keep changing from 00 to 59. Press button SET when you confirm the minute, then it will enter into the 12/24 time system mode.

hour setting

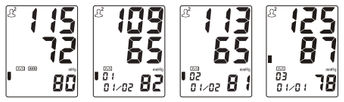
minute setting

4. 12/24 time system setting:
Continue to above step, the screen will display 12 or 24, press the button MEM to change 12 or 24 as you like, press button SET to exit setting mode and save the settings.

12/24 hour setting

Note:
Longly press the MEM button and the value quickly changes during setting process. You can stop the setting anytime when you press the button START/STOP to save the current setting and turn off.

About blood pressure

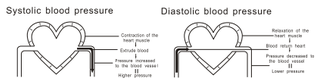


Memory-clear of measurements

If you are sure that you want to permanently remove all stored memories, please enter into memory reading mode, press and hold the SET button until CL NO showed on the display, press the button SET again to choose CL YES to clear all the memories , and press the START/STOP button to save the setting.

About blood pressure

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



Specification

Description	Automatic upper arm blood pressure monitor	
Display	LCD digital display	
Measuring principle	Oscillometric method	
Measuring localization	Upper arm	
Measurement range	Pressure	0~299 mmHg (0~39.9kPa)
	Pulse	40~180 pulses/min
Accuracy	Pressure	±3mmHg (±0. 4kPa)
	Pulse	±5% of reading
LCD indication	Pressure	3 digits display of mmHg
	Pulse	3 digits display
	Symbol	Memory/Average/IHB/Heartbeat/Low Battery,etc.
Cuff pressure	0-299 mmHg	
Memory function	2x99 sets memory of measurement values	
Power source	4pcs AA alkaline battery DC. 6V or USB 5V power supply	
Automatic power off	In 2 minutes	
Main unit weight	Approx. 224g(batteries not included)	
Main unit size	L129mm x W100mm x H68mm	
Main unit lifetime	10,000 times under normal use	
Battery life	Could be used for 300 times for normal condition	
Accessories	Cuff, instruction manual	
Operating environment	Temperature	10~40℃
	Humidity	15%~90%RH
	Air pressure	80kPa~105kPa
Storage environment	Temperature -20℃~55℃, Humidity :10% ~95% avoid crash, sun burn or rain during transportation.	
Blood Pressure Indication Range	SYS: 60~260mmHg	
	DIA: 30~200mmHg	

Note: the product can not be operated at an altitude of 2000m.

EMC Declaration

Guidance and manufacturer's declaration-electromagnetic emissions

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conduced RF IEC61000-4-6	150KHz to 80MHz：3Vrms 6Vrms (in ISM and amateur radio bands)80% Am at 1kHz	150KHz to 80MHz：3Vrms 6Vrms (in ISM and amateur radio bands)80% Am at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the digital blood pressure monitor, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: d=0.35\sqrt{P} d=1.2\sqrt{P}
Radiated RF IEC61000-4-3	10V/m, 80% Am at 1kHz	10V/m, 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, d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined 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:

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.

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 due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the digital blood pressure monitor is used exceeds the applicable RF compliance level above, the digital blood pressure monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the digital blood pressure monitor.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Proper use of the unit

Fitting the cuff

1）. Put the cuff on a table flatly with the velcro side down. Pass the end of the cuff through the metal loop so that a circle is formed. The velcro closer will now be facing outwards (ignore this step if the cuff has already been prepared) .

2）. Push the cuff over the left upper arm so that the tube points in the direction of the lower arm.

3）. Wrap the cuff on the arm as illustrated. Make certain that the lower edge of the cuff lies approximately 1 to 2 cm above the elbow and the rubber tube leaves the cuff on the inner side of the arm.

4）. Tighten the free end of the cuff and close the cuff by affixing the velcro.

5).The cuff should be snug on your upper arm so That you can fit 2 fingers between the cuff and your upper arm. Any piece of clothing restricts the arm which must be taken off.

6).Secure the cuff with the velcro closer in such a way that it lies comfortably and not too tight. Lay your arm on a table(palm upwards)so that the cuff is at the same height as the heart. Do not bend the tube.

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

Exceptional Situation

Error indicators

■ The following symbol will appear on the display when measuring abnormal.

Symbol	Cause	Correction
E-1	Weak signal, pressure change suddenly or the cuff pressure exceed 299 mmHg	Wrap the cuff properly.
		Remeasure with correct way.
E-2	External strong disturbance	When near cell phone or other high radiant device , the measurement will be failed.
		Keep quite and no chatting when measure.
E-3	It appears error during the process of inflating	Wrap the cuff properly.
		Make sure that the air plug is properly inserted in the unit.
		Remeasure.
E-5	Abnormal blood pressure	Repeat the measurement after relax for 30 mins , if get unusual readings for 3 times,please contact your doctor.
	Low battery	Replace all the worn batteries with new ones.

Trouble removal

Problem	Check	Cause and solutions
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	Insert 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 broken	Change a new cuff

⚠ Please contact the distributor if you can't solve the problem, do not disassemble the unit by yourself!

EMC Declaration

Guidance and manufacturer's declaration - electromagnetic emissions

The digital blood pressure monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the digital blood pressure monitor 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	±8 kV contact ±15 kV air	±8 kV contact ±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 %
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV input/output lines: ±1 kV	Power supply lines: ±2 kV input/output lines: ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV. line(s) to earth: ±2 kV. 100 kHz repetition frequency	line(s) to line(s): ±1 kV. line(s) to earth: ±2 kV. 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270 ° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270 ° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. means voltage prior to application of the test level.

EMC Declaration

Guidance and manufacturer's declaration–electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The digital blood pressure monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class [B]	The digital blood pressure monitor is suitable for use in all 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	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b)(W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380–390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380–390	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						
	1720	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
	1845						
	1970						
	2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240	5100–5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
	5240						
	5785						

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.

Digital Blood Pressure Monitor

WEONY (SHENZHEN) TECHNOLOGY CO., LTD.
3rd Floor B, Building 19, HeYi BeiFangYongFa Science & Technology Park, HeYi Community, ShaJing Street, BaoAn District, ShenZhen, 518104, P.R. China

EC REP Prolinx GmbH
Brehmstr. 56, 40239 Duesseldorf
Germany

CE 0123

REV:01.20190903
SOFTWARE VERSION:WBP101-A01