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Wrist Type Blood Pressure Monitor
Model Number: W1101L

USER MANUAL



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1.Introduction and Intended Use

It enables reliable measurement of systolic and diastolic blood pressure as well as pulse through the oscillometric method.

Before using, please read this instruction manual carefully and then keep it in a safe place.

1.1 Remember...

- Only a health-care professional is qualified to interpret blood pressure measurements.
- This device is NOT intended to replace regular medical checkups.
- Blood pressure readings obtained by this device should be verified before prescribing or making adjustments to any medications used to control hypertension. Under no circumstances should YOU alter the dosages of any drugs prescribed by your physician.
- This monitor is intended for use by adults only. Consult with a physician before using this instrument on a child.
- In cases of irregular heartbeat, measurements made with this instrument should only be evaluated after consultation with a physician.
- Host products, including accessories, shall be processed in accordance with local regulations after reaching the life cycle.

1.2 Warnings and Precautions



- Warning: The device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens). These can lead to temporary impairment of the measuring accuracy.
- Warning: The use of other accessories other than those specified or provided by the equipment manufacturer may cause electromagnetic radiation to increase or decrease electromagnetic immunity resulting in operational failure.
- Warning: This system may fail to yield specified measurement accuracy if operated or stored in temperature or humidity conditions outside the limits stated in the specifications section of this manual.
- Warning: Remove the battery if the ME EQUIPMENT is not likely to be used for some time.
- Warning: The user must check that the equipment functions safely and see that it is in proper working condition before being used.
- Warning: No modification of this equipment is allowed.
- Warning: The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- Warning: This equipment shall not be serviced or maintained while in use with the user.
- Warning: The user is an intended operator, the functions of monitoring blood pressure and pulse rate can be safely used by user. The routine clean and changing batteries can be performed by the user.

Caution: To avoid damaging the device, keep this unit away from children and pets.

Caution: The standard material used for the bladder and tubing is latex-free.

Attention: Self-measurement means control, not diagnosis or treatment. Unusual values must always be discussed with a physician. Under no circumstances should you alter the dosages of any drugs prescribed by a physician.

Attention: The pulse display is not suitable for checking the frequency of heart pacemakers!

Attention: In cases of irregular heartbeat, measurements made with this instrument should only be evaluated after consultation with a physician.

Attention: The temperature of contact parts with the user is as high as 41.3 °C, and the contact time is less than 10 minutes.

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

Note: The cuff is treated as the applied part. The user should contact the manufacturer for assistance, if needed, in setting up, using or maintaining the device.

Note: Do not attempt to service or repair this device yourself. Should a malfunction occur, refer to local distributor or the manufacturer.

2. Important Information on Blood Pressure and Its Measurement

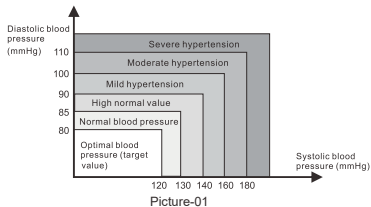
2.1. How does high or low blood pressure arise?

Your level of blood pressure is determined in the circulatory center of the brain and adjusts to a variety of situations through feedback from the nervous system. To adjust blood pressure, the strength and speed of the heart (Pulse), as well as the width of circulatory blood vessels is altered. Blood vessel width is controlled by fine muscles in the blood vessel walls.

Your level of arterial blood pressure changes periodically during heart activity: During the "blood ejection" (Systole) the value is highest (systolic blood pressure value). At the end of the heart's "rest period" (Diastole) pressure is lowest (diastolic blood pressure value).

2.2. Which values are normal?

Please refer to the diagram below (Picture-01)



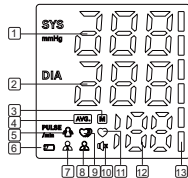
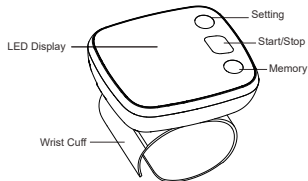
There are six grids in the display of device. Please refer to the picture-01-01. Different grids represent different interval scales of WHO.

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

Picture-01-01

3. Components of Your Blood Pressure Monitor

3.1. Measuring unit



3.2 The symbols on the LED display

- | | |
|-------------------------------|---------------------------------|
| 1. Systolic blood pressure | 2. Diastolic blood pressure |
| 3. Memory symbol | 4. Average value symbol |
| 5. Movement error symbol | 6. Low battery symbol |
| 7. User 1 | 8. User 2 |
| 9. Irregular heartbeat symbol | 10. Mute symbol |
| 11. Heartbeat symbol | 12. Pulse display/Memory number |
| 13. WHO symbol | |


3.3. Features of Model W1101L

1. Average value function
2. Double users: 2 x 120 sets memory
3. WHO indicator
4. Irregular heartbeat checking
5. Auto power-off
6. Low battery display
7. Body movement detecting

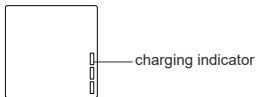
4. Using Your Monitor for The First Time

4.1 Battery Power checking

The battery is built-in chargeable Lithium battery.

Press the "START/STOP" button, if the symbol () is blinking and the device speaks "battery low power, please recharge it". It means the battery power is low and need to be recharged.

During the charging process, the charging indicator on the display screen blinks. When the charging indicator stops blinking. It means the battery power is fully charged.



4.2. System Settings

Before setting, ensure that the battery power is enough.

When the device is in sleep mode, long press the SET button for more than 3s, and then you can start to set.

Setting the User ID(1 or 2):

When the User ID is flashing, and then you can switch the User ID by pressing the MEM button, once the User ID set is OK, press the SET button to confirm.

Setting Volume:

When display with SP is flashing, press the MEM button to switch volume 1, volume 2, volume 3 or OFF. Press the SET button to confirm. After the setting is completed, the device switches off automatically and save the setting result.

When the device is in sleep mode, short press the SET button to wake the display. When the User ID appears, press SET again to switch voice on/off.

5. Measurement Procedure

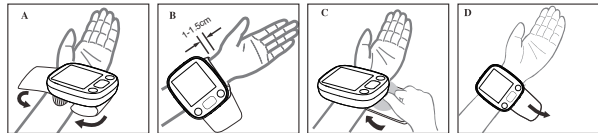
5.1. Before measurement:

- Avoid eating and smoking as well as all forms of exertion directly before measurement. These factors influence the measurement result. Find time to relax by sitting in an armchair in a quiet atmosphere for about ten minutes before taking a measurement.
- Remove any garment that fits closely to your wrist.
- Always measure on the same wrist (normally left).

5.2. Fitting the Cuff

Please refer to picture-04

- a) Remove all jewelry and watches. The palm of your hand should be facing you. Apply the cuff so that the display is facing you.
- b) The distance between the cuff and the hand should be 1-1.5cm.
- c) Secure the cuff with the hook and loop adhesive so that it lies comfortably and not too tight. It should be comfortable.
- d) Lay your arm on a table with your palm upwards. Support your arm with a cushion so that the cuff rests at about the same height as the heart. Remain still for 2 minutes, sitting quietly, before beginning a measurement.



Picture-04

5.3. Measure Procedure

The device is designed to take measurements and store the measurement values in memory for two people using User ID 1 and User ID 2.

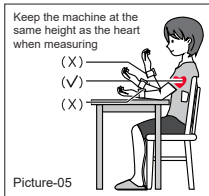
Refer to picture-05

1. Sit comfortably in a chair with your feet flat on the floor.

2. Select your User ID (1 or 2).

Stretch your arm forward on the desk and keep relaxing, make sure the palm of hand is upturned. Make sure wrist is in correct position, to avoid body movement. Sit still and do not talk or move during the measurement.

After the cuff has been appropriately positioned on the wrist and connected to the blood pressure monitor, the measurement can begin:




Picture-05

Operate on the device

- a) Press the START/STOP button. The pump begins to inflate the cuff. In the display, the increasing cuff pressure is continually displayed.
- b) After automatically reaching an individual pressure, the pump stops and the pressure slowly falls. The cuff pressure is displayed during the measurement.
- c) When the device has detected your pulse, the heart symbol in the display begins to blink.
- d) When the measurement has been concluded, the measured systolic and diastolic blood pressure values, as well as the pulse will be displayed.
- e) The measurement results are displayed until you switch the device off. If no button is pressed for 60 seconds, the device switches off automatically.

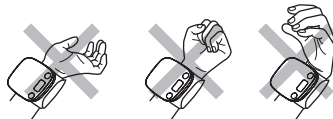
f) Movement error symbol ()

The Movement Error Symbol () is displayed if you move your body during the measurement. Please remove the cuff, and wait 2-3 minutes. Reapply the cuff and take another measurement.

NOTE:

User Position:

- 1) Comfortably seated
- 2) Legs uncrossed
- 3) Feet flat on the floor
- 4) Back and arm supported
- 5) Middle of the CUFF at the level of the right atrium of the heart
- 6) Relax your wrist and hand. Do not bend your wrist back, clench your fist, or bend your wrist forward. Refer to Picture-06




Picture-06

Recommended Use Methods

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

5.4. Irregular Heartbeat Detector

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

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

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

This instrument is an oscillometric blood pressure monitor device that also analyzes pulse frequency during measurement. The instrument is clinically tested.


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


a) Press the START/STOP button, the pump begins to inflate the cuff. In the display, the increasing cuff pressure is continually displayed.


b) After automatically reaching an individual pressure, the pump stops and the pressure slowly falls. The cuff pressure is displayed during the measurement.

c) When the device has detected your pulse, the heart symbol in the display begins to blink.

d) When the measurement has been concluded, the measured systolic and diastolic blood pressure values, as well as the pulse will be displayed.

e) The appearance of this  symbol signifies that an irregular heartbeat was detected. This indicator is only a caution. It is important that you be relaxed, remain still and do not talk during measurements.

f) Movement error symbol ()


The Movement Error Symbol () is displayed if you move your body during the measurement. Please remove the cuff, and wait 2-3 minutes. Reapply the cuff and take another measurement.

5.6. Error Indicates

SYMBOL	CAUSE	CORRECTION
No display appears	Weak battery	Please connect to power and charge the device.
Er1	Sensor abnormal	Check if the pump is working or not. If it is working, then the problem is sensor abnormal. Please contact your retailer or seller for support.
Er2	Monitor could not detect pulse wave or cannot calculate the blood pressure data	Start the measurement again.If the error is still displayed, Please contact your retailer or seller for support.
Er3	Measurement result is abnormal	Occasionally-measure for one more time/ Always - Please contact your retailer or seller for support.
Er4	Too loose cuff or air leakage (Cannot inflate to 30mmHg within 15s)	Tie the cuff correctly and make sure the air plug is properly inserted in the unit
Er5	The air tube is crimped	Correct it and make the measurement again
Er6	The sensor is sensing great fluctuation in the pressure	Please keep quiet and don't move
Er7	The pressure that the sensor sensing is over the limit	Start the measurement again.If the error is still displayed, Please contact your retailer or seller for support.
Er8	The demarcation is incorrect or the device has not been demarcated	Please contact your retailer or seller for support















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

Trouble removal

Problem	Check	Cause and solutions
No power	Check the battery power	Recharge the unit
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 during measurement
Cuff leak	Whether the cuff wrap too loose	Wrap the cuff tightly
	Whether the cuff is broken	Change a new cuff
Readings appear too high or too low	Blood pressure varies constantly. Many factors including stress, time of day, and/or how you apply the wrist cuff, may affect your blood pressure. Review sections 5.1 - 5.3 and chapter 6.	
Any other problems occur	Press the [START/STOP] button to turn the monitor off, then press it again to take a measurement. If the problem continues, please contact your retailer or seller for support	
 Please contact the distributor if you can't solve the problem, do not disassemble the unit by yourself!		

SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the Digital Blood Pressure Monitor W1101L, or on its accessories. Some of the symbols represent standards and compliances associated with the wrist type blood pressure monitor W1101L and its use.

	Authorized Representative in the European Community		
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.		CE Mark
	Date of manufacture.		Put up
	Manufacturer		Keep dry
SN	Specifies serial number		Fragile
	Type BF applied part		Avoid the sun
	Direct current		Handle gently
	Follow instructions for use		Temperature range
No Sterilize requirement			
Not category AP / APG equipment			
Mode of operation: continuous			

5.6. Memory

Each unit stores 120 sets measurements for 2 users, totally 240 sets (User 1 and 2). Measurements for each user are stored separately. Be certain that you are viewing the measurements for the correct user.

A.View the memory:

When the device is in sleep mode, press the MEM button. The monitor will display User ID and an average value of the last 3 times measurements stored in the unit. (If measurements are less than 3 sets, directly display the first set).

Each time you press the MEM button, it will display the memory value from the latest to the oldest in turn.

B.Delete memory:

In average value memory viewing mode, the average value symbol (AVG) is being displayed, long press the MEM button for 3 seconds, then it will delete all measurements for the current user.

In single set memory viewing mode, long press the MEM button for 3 seconds, then it will delete only a set measurement being displayed.

Note: If you decide to delete the all memory, please keep the memory in another way, incase you need it some days later. Take the battery out won't lead to a memory missing.

5.7. Discontinuing a Measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g the user feels unwell), the Start/Stop button can be pressed at any time. The device then immediately lowers the cuff pressure automatically.

6. Care and Maintenance

Wash hands after each time measurement.

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

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

6.1. Accuracy test

Sensitive measuring devices must be checked for accuracy from time to time. We recommend a periodical inspection of your unit by an authorized dealer every 1 year. Please turn to local distributor or the manufacturer.

7. Warranty

Your blood pressure monitor is guaranteed for 2 years against manufacturers' defects for the original purchaser only, from date of purchase. The warranty does not apply to damage caused by improper handling, accidents, professional use, not following the operating instructions or alterations made to the instrument by third parties.

Warranty only applies to the main device and its cuff. All other accessories are not covered by warranty.

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

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

8. Certifications

Device standard:

This device is manufactured to meet the European blood pressure monitors:

IEC 80601-2-30/ ISO81060-1/ IEC60601-1-11/ IEC60601-1

Electromagnetic compatibility:

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

9. Technical Specifications

Model: W1101L

Weight: 101g

Display: 45×45mm 【1.77"×1.77"】 LED Digital Display

Size: 78 (W)×67 (L)×22.2 (H) mm 【3.12"(W)×2.75"(L)×0.98"(H)】

Accessories: 1×Main Device, 1×Users Manual, 1× Type-c Cable, 1× Quick Start Guide

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

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

Atmospheric pressure range: 70kPa~106kPa

Measuring method: Oscillometric

Pressure sensor: Resistive

Measuring range: DIA: 40-130mmHg; SYS: 60-230mmHg

Pulse: 40 to 170 beats per minute

Cuff pressure display range: <300mmHg

Memory: Automatically stores the last 120 measurements for 2 users (total 240)

Measuring resolution: 1 mmHg

Accuracy: Pressure within ± 3 mmHg / pulse ± 5 % of the reading

Power source: Built-in high capacity lithium battery - 300mAh

Cuff : 4.92"-8.46" (12.5-21.5cm)

Users: Adult

Expected service life of the device and accessories: 5 years

Technical alterations reserved!

10. EMC Declaration

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: 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.

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 improper operation.

Warning: 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 Wrist Type Blood Pressure Monitor (model: W1101L), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

Technical description

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

2. Guidance and manufacturer's declaration-electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV input/output lines: ±1 kV	Not application
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV. line(s) to earth: ±2 kV. 100 kHz repetition frequency	Not application
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	Not application
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	Not application
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz

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

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	MoModulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380-390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27
	450	380-390	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710	704-787	LTE Band 13,17	Pulse Modulation 217 Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3 4,25;UMTS	Pulse Modulation 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9
5240							
5785							