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Version Number:1.0

Fully Automatic Digital Wrist

Blood Pressure Monitor

Model Number: W02

USER'S MANUAL

CONTENTS

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

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 patient is as high as 41.3 ℃, 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.

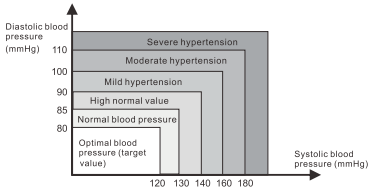
Note: Do not attempt to service or repair this device yourself. Should a malfunction occur, refer to local distributor or the manufacturer.

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.

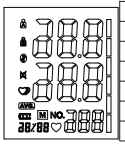
Your level of arterial blood pressure changes periodically during heart activity: During the “blood ejection” (Systole) the value is highest (systolic blood pressure value). At the end of the heart’s “rest period” (Diastole) pressure is lowest (diastolic blood pressure value).

2.2. Which values are normal?
Please refer to the diagram below(Picture-01)



Picture-01

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

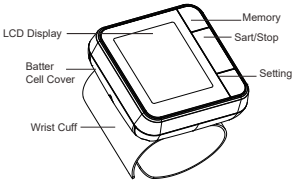


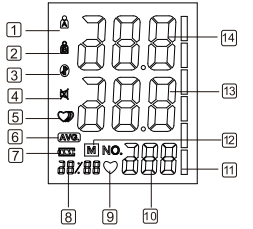
Blood pressure value	WHO grids in device	WHO Classification
DIA<80 & SYS<120	1	Optimal blood pressure
DIA<85 & SYS<130	2	Normal blood pressure
DIA<90 & SYS<140	3	High normal value
DIA<100 & SYS<160	4	Mild hypertension
DIA<110 & SYS<180	5	Moderate hypertension
DIA>=110 or SYS>=180	6	Severe hypertension

Picture-01-01

3. Components of your blood pressure monitor

3.1. Measuring unit





3.2 The symbols on the LCD display

1. User A
2. User B
3. Bluetooth symbol
4. mute symbol
5. Irregular heartbeat symbol
6. Low battery symbol
7.Average value symbol
8. Date/Time display
9. Heartbeat symbol
10. Pulse display
11.WHO symbol
12. Memory symbol
13. Diastolic blood pressure
14.Systolic blood pressure

3.3. Features of Model W02

1.Talking function
2. Double users: 2 x 120 sets memory
3.Date/time display
4. Irregular heartbeat checking
5. Average value function
6. Low battery display
7. WHO function
8. Auto power-off
9. Volume adjustment

4.Using your Monitor for the First Time

4.1Activating the pre-installed batteries

Battery Installation

Use only 1.5V “AAA” alkaline batteries with this device.

1. Press the hook on the bottom of the battery cover and lift the cover off in the direction of the arrow.

2. Install 2 “AAA” size batteries so the + (positive) and - (negative) polarities match the polarities of the battery compartment, replace the battery cover.Make sure that the battery cover is securely in position.

Battery replacement

Low Battery Indicator

1.When the Low Battery Indicator appears on the display, turn the monitor off and remove all the batteries. Replace with 2 new batteries at the same time. Long-life alkaline batteries are recommended.

2.To prevent the damage of monitor from leaked battery fluid, please take out of battery if the monitor unused in a long time(generally more than 3 months). If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Contact a physician immediately.

3. Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

4.2. System Settings

After you load the battery ,long press the SET button for more than 3s, and then you can start to set.

Setting the User:

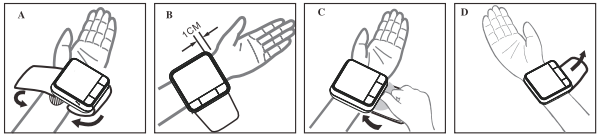
Press the MEM button to select User A or User B. When display A (/B) on the screen, press the MEM button to switch to user B (/A). Press the SET button to confirm.

Setting the Year:
When the year display is flashing, press the MEM button continuously and it will increase continuously 1 by 1 until 2049, and then return the original year , once the year set is OK, press SET button to confirm.
Setting Month/Date:
Initial Month/Date is 1/01, when the Month display is flashing, press the MEM button, the month will increase by 1, press SET button to confirm, and do in the same way to set the date. Press SET button to confirm.
Setting Time :
When the hour display is flashing, press the MEM button, the hour will increase by 1, press SET button to confirm, and do in the same way to set the minute. Press SET button to confirm.
Setting Volume:
When display with SP is flashing, press MEM button to switch ON or OFF. Press SET button to confirm.
C.Record Delete:
When you checking the memory data, long press MEM button to delete existing user measurement data.
Note:
You can't delete all measurement record from the monitor storage at one time, if you decide to delete the all record, please keep the record in another way, in case you need it some days later. Take the battery out won't lead to a record missing.

5. Measurement Procedure

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 1cm.
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

Refer to picture-05

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

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

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

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.

NOTE:

Patient Position:

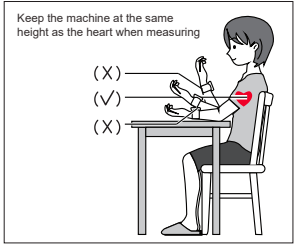
1) Comfortably seated
2) Legs uncrossed
3) Feet flat on the floor
4) Back and arm supported
5) Middle of the CUFF at the level of the right atrium of the heart

Recommended Use Methods

1.Recommendation that the PATIENT relax as much as possible and not talk during the measurement PROCEDURE

2.Recommendation that 5 min should elapse before the first reading is taken

3.Any reading can be affected by the measurement site, the position of the PATIENT, exercise, or the PATIENT'S physiologic condition
4.Performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude
5.To stop the inflation or measurement, push the START/STOP button. The monitor will stop inflating, start deflating, and will turn off.
6.After the monitor has detected your blood pressure and pulse rate, the cuff automatically deflates. Your blood pressure and pulse rate are displayed.
7.The monitor will automatically turn off after one minute.



Picture-05

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 patient to seek medical advice. The instrument does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

5.6. Error Indicates

SYMBOL	CAUSE	CORRECTION
No display appears	Weak battery or improper placement	Replace both batteries with new ones. Check the battery installation for proper placement of the battery polarities.
Er1	Sensor abnormal	Check if the pump is working or not. If it is working, then the problem is sensor abnormal. Please send it to the local distributor.
Er2	Monitor could not detect pulse wave or cannot calculate the blood pressure data	Check if the air releasing is too slow or not. If it is too slow, please check if there is any dust in the tube plug of the cuff and the cuff port in the device. If yes, please clean and start the measurement again. If no, please send the device back to the local distributor.
Er3	Measurement result is abnormal (SYS≦45mmHg, DIA≦24mmHg)	Occasionally-measure for one more time/ Always - send it to local distributor
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	Please send back to the local distributor
Er8	The demarcation is incorrect or the device has not been demarcated	Please send back to the local distributor

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

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 is broken	Change a new cuff

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

SYMBOL DESCRIPTIONSt

The following symbols may appear in this manual, on the Digital Blood Pressure Monitor W02, or on it's accessories. Some of the symbols represent standards and compliances associated with the Digital Blood Pressure Monitor W02 and its use.

EC REP	Authorized Representative in the European Community
CE 0123	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Date of manufacture.
	Manufacturer
SN	Specifies serial number
	Type BF applied part
⎓	Direct current
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
	Follow instructions for use

	Put up
	Keep dry
	Fragile
	Avoid the sun
	Handle gently
	Temperature range
No Sterilize requirement	
Not category AP / APG equipment	
Mode of operation: continuous	

5.6. Memory

At the end of a measurement, this monitor automatically stores each result with date and time. Each unit stores 120 sets measurements for 2 users, totally 240 sets（User A and B）.

Viewing the stored values

With the unit off, press the Memory button. The display first shows "A", then shows an average of all measurements stored in the unit. Please note: Measurements for each user are averaged and stored separately. Be certain that you are viewing the

measurements for the correct user. Pressing the Memory button again displays the previous value. To view a particular stored memory, press and hold the Memory button to scroll to that stored reading.

5.7. Discontinuing a Measurement

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

5.8. Battery Change Indicator

Batteries discharged– replacements required

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

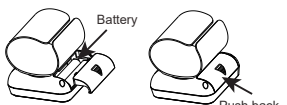
The battery compartment is located on the back side of the unit.

a) Remove cover from the bottom plate, as illustrated below picture-06

b) Insert the batteries (2 x size AA A). Always use AAA long life batteries or alkaline 1.5v batteries.

c) The memory retains all values although date and time must be reset - the year number therefore flashes automatically after the batteries are replaced.

d) To set date and time, follow the procedure described in Section 4.2.



Picture-06

6. Care and Maintenance

Wash hands after each time measurement.

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

a) Do not expose the device to either extreme temperatures, humidity, dust or direct sunlight.

b) The cuff contains a sensitive air-tight bubble. Handle this cuff carefully and avoid all types of stress through twisting or buckling.

c) Clean the device with a soft, dry cloth. Do not use gas, thinners or similar solvents. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff with bladder must not be washed in a dishwasher, clothes washer, or submerged in water.

d) Handle the tube carefully. Do not pull on it. Do not allow the tubing to kink and keep it away from sharp edges.

e) Do not drop the monitor or treat it roughly in any way. Avoid strong vibrations.

f) Never open the monitor! This invalidates the manufacturer's warranty.

g) Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

6.1. Accuracy test

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

7. Warranty

Your blood pressure monitor is guaranteed for 1 year against manufacturers' defects for the original purchaser only, from date of purchase. The warranty does not apply to damage caused by improper handling, accidents, professional use, not following the operating instructions or alterations made to the instrument by third parties.
Warranty only applies to the 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 / IEC60601-1-11 / IEC60601-1
Electromagnetic compatibility:
Device fulfills the stipulations of the International standard
IEC60601-1-2

9. Technical Specifications

Model: W02
Weight: 101g (Batteries are not included)
Display: 41.5*49.5mm 【1.63"x1.95"】LCD Digital Display
Size: 68 (W) x 68 (L) x 30 (H) mm【2.68"(W)x2.68"(L)x1.18"(H)】
Accessories: 1×Main Device, 1×Cuff, 1×Users manual,
Operating Conditions: Temperature: 5℃ to 40℃;Humidity: 15% to 93% RH;
Storage And Shipping Conditions:Temperature: -25℃ to 70℃; 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 199 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: 2*AAA batteries, 1.5 V
Cuff : 4.92"-8.64" (12.5-21.5cm)
Automatically power off : 60 seconds
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 Blood Pressure Monitor (model: W02), 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
Conduced 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. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
	Test Frequency (MHz)	Band (MHz)	Service	MoModulation	Modulation (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 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						