



User Manual

Wrist Blood Pressure Monitor WS-380



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zewa

- Thank you very much for selecting ZEWA Wrist Blood Pressure Monitor WS-380.
- To use the monitor correctly and safely, please read the manual thoroughly.
- Please keep this manual well in order to reference in future.

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♥ General Description

Thank you for selecting ZEWA Blood Pressure Monitor (WS-380).
The monitor features blood pressure measurement, pulse rate measurement and the result storage.
Readings taken by the WS-380 are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.
This manual contains important safety and care information, and provides step by step instructions for using the product.
Read the manual thoroughly before using the product.

Features:

- Systolic blood pressure
- Diastolic blood pressure
- Pulse rate
- 60 records for one user

♥ Indications for Use

The ZEWA Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate with a wrist circumference ranging from 13.5cm to 21.5 cm (about 5½"-8½"). It is intended for adult indoor use only.

♥ Contraindications

- 1.The device should not be used by any person who may be suspected of, or is pregnant.
- 2.The device is not suitable for use on patients with implanted electrical devices, such as cardiac pacemakers, defibrillators.

♥ Measurement Principle

This product uses the Oscillometric Measuring Method to detect blood pressure. Before every measurement, the unit establishes a "zero point" equivalent to the atmospheric pressure. Then it starts inflating the cuff. Meanwhile, the unit detects pressure oscillation generated by beat-to-beat pulsatile, which is used to determine the systolic pressure and diastolic pressure as well as pulse rate.

♥ Safety Information

The signs below might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Symbol for "THE OPERATION GUIDE MUST BE READ"		Symbol for "TYPE BF APPLIED PARTS"
	Caution: These notes must be observed to prevent any damage to the device.		Symbol for "ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice"
	Symbol for "MANUFACTURER"		Symbol for "DIRECT CURRENT"
	Symbol for "SERIAL NUMBER"		Symbol for "MANUFACTURE DATE"
	Symbol for "RECYCLE"		
	The Green Dot is the license symbol of a European network of industry-funded systems for recycling the packaging materials of consumer goods.		

! CAUTION

- * This device is intended for adult use in homes only.
- * The device is not suitable for use on neonatal patients, pregnant women, patients with implanted, electronical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses.
- * The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
- * The device is not intended for patient transport outside a healthcare facility.
- * The device is not intended for public use.
- * This device is intended for no-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the wrist or for functions other than obtaining a blood pressure measurement.
- * Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not begin or end medical treatment without asking a physician for treatment advice.
- * If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.
- * Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
- * When the device is used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result.
- * Warning: Do not apply the cuff over a wound; otherwise it can cause further injury.
- * Do not inflate the cuff on the same limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.

**CAUTION**

- *On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure > 300mmHg or constant pressure > 15mmHg for more than 3 minutes) applied to the wrist may lead to an ecchymosis.
- *Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
- * When measurement, please avoid compression or restriction of the connection tubing.
- * The device cannot be used with HF surgical equipment at the same time.
- * The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.
- * To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
- * This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
- * Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
- * This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's wrist and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
- * When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
- * This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
- *This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.
- * The maximum temperature that the applied part can be achieved is 42.5 °C while the environmental temperature is 40 °C.
- * The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- * Warning: No servicing/maintenance while the ME equipment is in use.
- * The patient is an intended operator.

**CAUTION**

- * The patient can measure, transmit data and change batteries under normal circumstances and maintain the device and its accessories according to the user manual.
- * To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
- * The blood pressure monitor and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
- * During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensation or irritation reaction.
- * If you experience discomfort during a measurement, such as pain in the wrist or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your wrist.
- * If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressure reaches 40 kPa (300 mmHg), detach the cuff from the wrist and press the START/STOP button to stop inflation.
- * Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
- * Do not wash the cuff in a washing machine or dishwasher!
- * The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
- * It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
- * Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, etc., to assist to service personnel in parts repair.
- * The operator shall not touch output of batteries and the patient simultaneously.

**CAUTION**

- * Cleaning :Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
- * The device doesn't need to be calibrated within two years of reliable service.
- * If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of ZEWA. Don't open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
- * Please report to ZEWA if any unexpected operation or events occur.
- * Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
- * Be careful to strangulation due to cables and hoses, particularly due to excessive length.
- * At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
- * This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
- * Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the MANUFACTURER from the 80MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.
- * Please use ACCESSORIES and detachable parts specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
- * There is no luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
- * Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

♥ LCD Display Symbol

SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic pressure	High blood pressure
DIA	Diastolic pressure	Low blood pressure
PUL	Pulse display	Pulse in beats per minute
	Motion indicator	Motion may result in an inaccurate measurement
	Low battery	Batteries are running low and need to be replaced

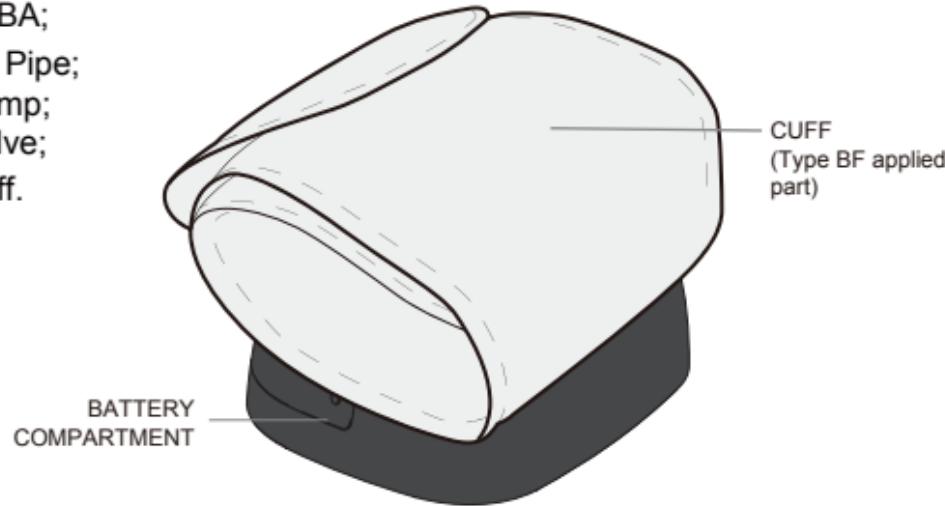
SYMBOL	DESCRIPTION	EXPLANATION
kPa	kPa	Measurement unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement unit the blood pressure (1mmHg=0.133kPa)
⌚	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.
00:00	Current time	Month/Day,Hour/Minute
Avg	Average value	The average value of lastest 3 groups blood pressure
❤	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
🔍	Memory	Indicate it is in the memory mode
👤	User 1	Start measurement and save the results for user 1
👤	User 2	Start measurement and save the results for user 2
█	Blood pressure level indicator	Indicate the blood pressure level
!	Data storage	Indicate the data is waiting to be transmitted.
uetooth	Bluetooth icon	Indicate the Bluetooth is working.

♥ Monitor Components



Component list of pressure measuring system:

1. PCBA;
2. Air Pipe;
3. Pump;
4. Valve;
5. Cuff.

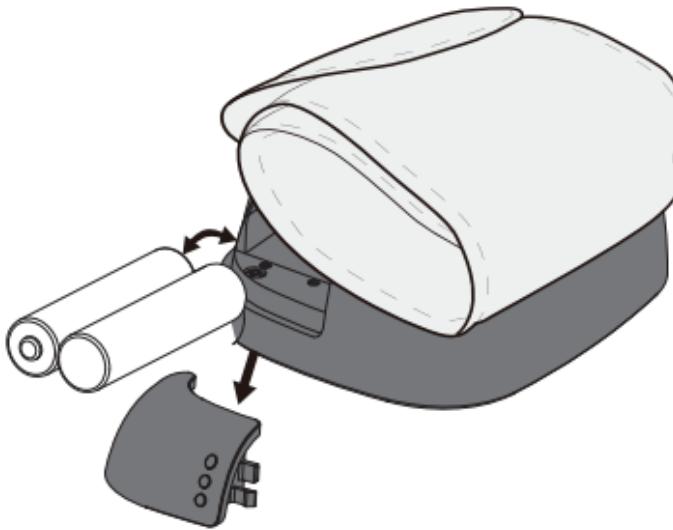


♥ List

- 1) Blood Pressure Monitor WS-380
- 2) 2×AAA batteries
- 3) User manual

♥ Installing and Replacing the Batteries

- Slide off the battery cover.
- Install the batteries by matching the correct polarity, as shown below. Always use the correct battery type (2×AAA batteries.)
- Replace the cover.



Replace the batteries whenever the below happens

- The  +Lo shows
- The display is dim.
- The display does not light up



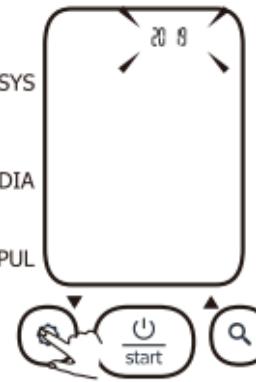
CAUTION

Do not use new and used batteries together.
 Do not use different types of batteries together.
 Do not dispose the batteries in fire. Batteries may explode or leak.
 Remove batteries if the device is not likely to be used for some time.
 Worn batteries are harmful to the environment. Do not dispose with daily garbage.
 Remove the old batteries from the device following your local recycling guidelines.

♥ Setting Date, Time, Positioning Symbol and Measurement Unit

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of year is 2019 ~ 2059. Time format: 24H)

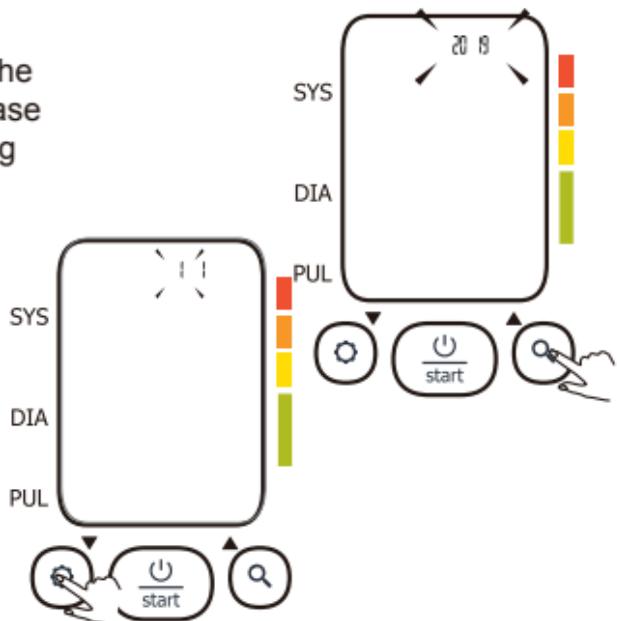
1. When the monitor is off, press “



Notes:

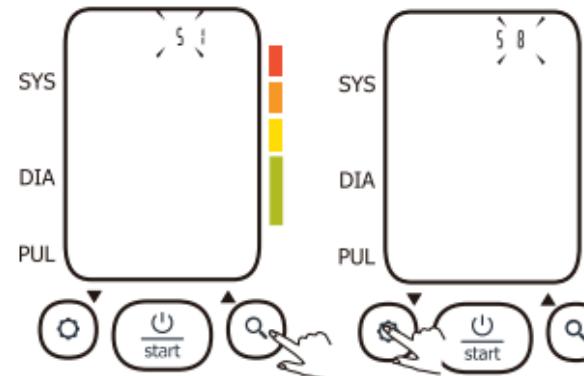
1. During the process of setting, you can press “” button to stop setting at any time.
2. If there is no operation during the process of setting, it will turn off within 1 minute.

2. Press “” button to change the [YEAR]. Each press will increase the numeral by one in a cycling manner.

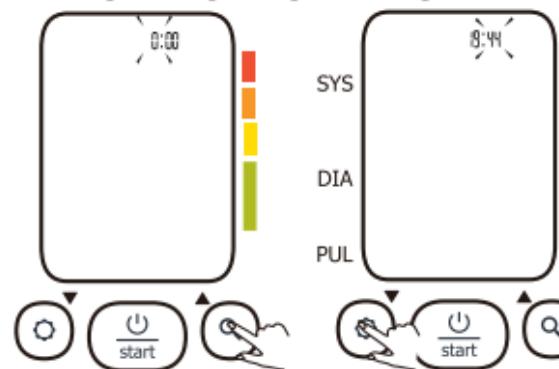


3. When you get the right year, press “” button to confirm and it will turn to next step.

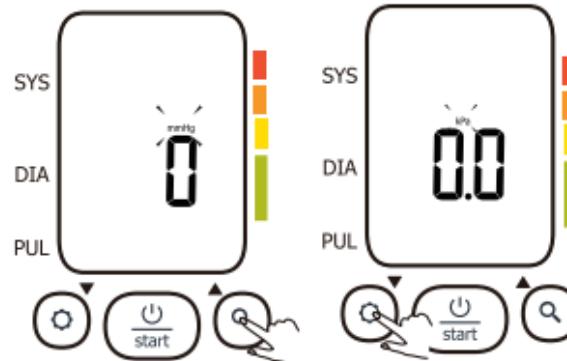
4. Repeat step 2 and 3 to confirm [MONTH] and [DAY].



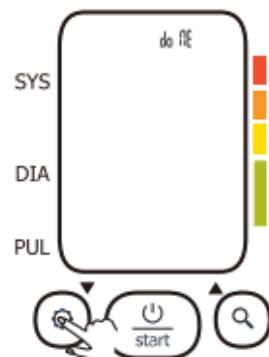
- 5 2 and 3 to confirm [HOUR] and [MINUTE].



6. Repeat step 2 and 3 to confirm the measurement unit.



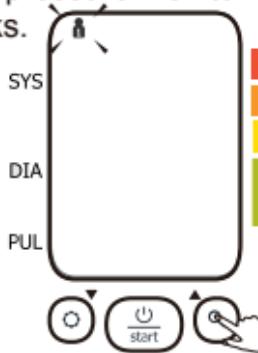
7. After confirming the measurement unit, the LCD will display "done", then the monitor will turn off.



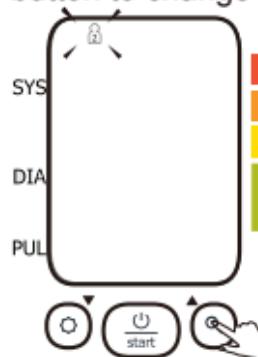
♥ Select the User ID

Before you start the measurement, please select the desired user ID first.

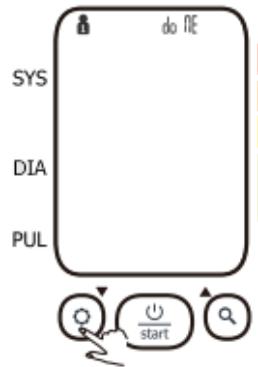
1. When the blood pressure monitor is off, press and hold "Q" button until the user ID blinks.



2. Then press "Q" button to change the user ID between user 1 and user 2.



- 3.** Press " SET " button to confirm your selection , the LCD will display "User ID+donE" and then turn off.



♥ Tie the Cuff

1. Remove all accessories (watch, bracelet,etc) from your wrist. If your physician has diagnosed you with poor circulation in your wrist, use the other one.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your wrist with your palm facing up.
4. Position the edge of the cuff about 1cm~1.5cm from wrist joints.
5. Fasten the wrist cuff around your wrist, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.
6. Sit comfortably with your tested wrist resting on a flat surface. Place your elbow on a table so that the cuff is at the same level as your heart. Turn your palm upwards. Sit upright in a chair, and take 5-6 deep breaths.
7. Patients with Hypertension:

The middle of the cuff should be at the level of the right atrium of the heart; Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and wrist supported.
Rest for 5 minutes before measuring.

Wait at least 3 minutes between measurements. This allows your blood circulation to recover.

Take the measurement in a silent room.

The patient must relax as much as possible and do not move and talk during the measurement procedure.

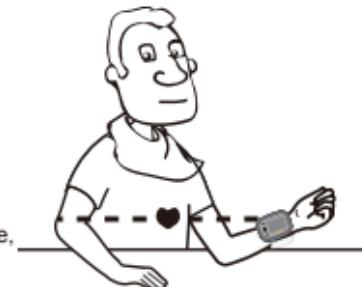
The cuff should maintain at the same level as the right atrium of the heart.

Do not cross your legs and keep your feet on the ground.

Keep your back against the backrest of the chair.

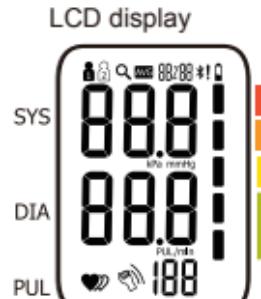
For a meaningful comparison, try to measure under similar conditions.

For example, take daily measurements at approximately the same time, on the same wrist, or as directed by a physician.

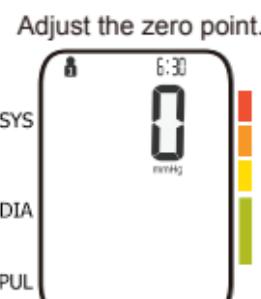
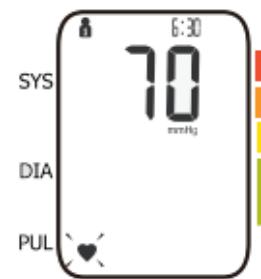


♥ Start the Measurement

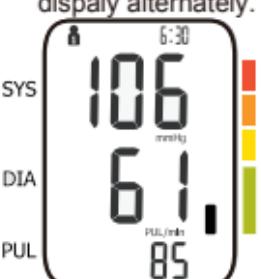
1. When the monitor is off, press “” button to turn on the monitor, and it will finish the whole measurement. (Take user 1 for example.)



Inflating and measuring.



Display and save the result.
The year, date and time will display alternately.



2. After finishing the measurement, the LCD displays the blinking icon ‘’, and transmits the data.

Note:

- (1). The symbol “” will disappear after successful data transmission, and you may check your personal health data stored in your mobile device.
- (2). If the data transmission fails, the symbol “” will remain. The pending measurement data will be transmitted to your mobile device when next measurement is complete.

3. During the measurement or when the measurement is finished, press “”button to turn off the monitor. Otherwise it will power off in one minute.

Tips:

1. There are two users in total. Each user has 60 records.
2. You can press “” button to stop measuring during the process of the measurement at any time.
3. If the measurement result is out of the measurement range (SYS: 60mmHg to 230mmHg; or DIA: 40mmHg to 130mmHg; or Pulse: 40-199 pulse/minute), the LCD will display “out”.

CAUTION

- Interference may occur in the vicinity of equipment marked with the following symbol (⚠). And WS-380 may interfere with nearby electrical equipment.
- Sensitive people, including pregnant women pre-eclampsia and those who have implanted medical electronic instruments, should avoid using the unit whenever possible.
- Keep the monitor at least 20 centimeters away from the human body (especially the head) when the data transmission is proceeding after measurement.
- To enable the data transmission function, this product should be paired to Bluetooth end at 2.4 GHz.

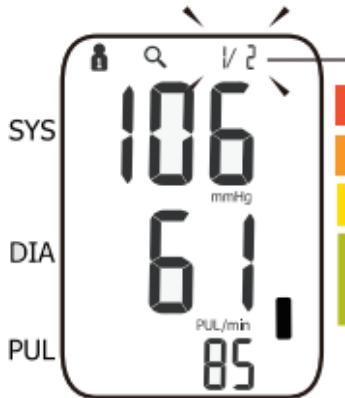
How to mitigate possible interference?

- The range between the device and BT end should be reasonably close, from 1 meter to 10 meters. Please ensure no obstacles between the device and BT end so as to obtain quality connection and to lower the RF output range.
- To avoid interference, other electronic devices (particularly those with wireless transmission / Transmitter) should be kept at least 1 meter away from the monitor.

Recall the Records

1. When the monitor is off, press “Q” button to show the average value of the latest three measurement records. If the records are less than 3 groups, it will display the latest record instead.

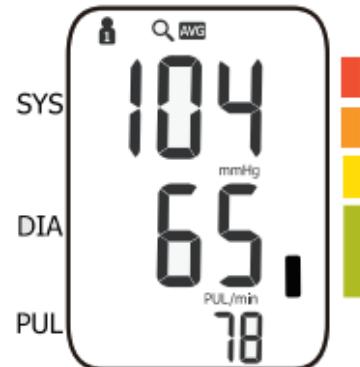
2. Press “Q” button or “O” button to get the record you want.



SYS

DIA

PUL



SYS

DIA

PUL

6:35

The corresponding date is 25th December.

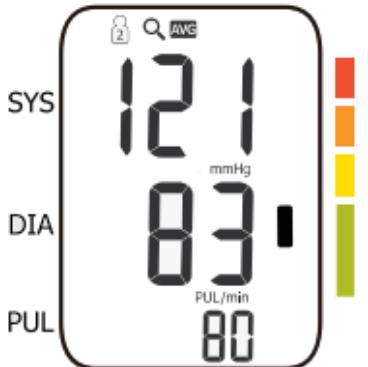
1/2

The record number is No.1. Two records in total.

12:25

The record number, date and time of the measurement records will display alternately.

3. If you want to check the other user's measurement records, please press “” button to turn off the blood pressure monitor. Then press and hold “Q” button to enter the selecting user mode, press “Q” again to change the user, when the desired user ID blinks, press “O” button to confirm. Then press “Q” button to check the records of the selected user.



CAUTION

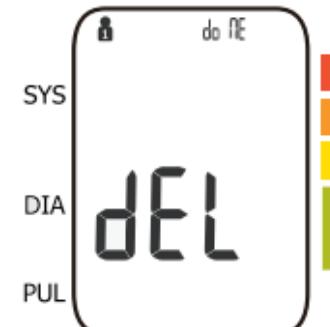
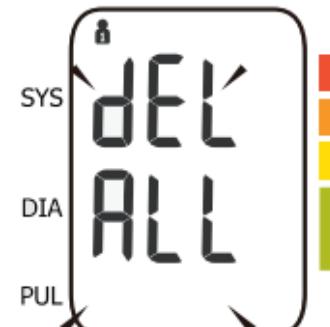
The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

Delete the Records

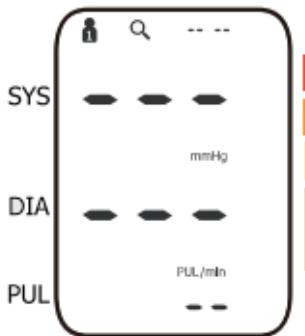
If you did not get the correct measurement, you can delete all the results for the selected user by following steps. (Take user 1 for example.)

1. Hold pressing “Q” button about 3 seconds when the monitor is in the memory recall mode , the “dEL All +User ID ” will flash on the display.
2. Press “O” button to confirm ,the LCD displays “User ID+dEL donE” and then turn off.

Note: To exit out the delete mode without deleting any records, press “” button before pressing “O” button to confirm any delete commands.



3. If there is no record, press "Q" button he below display will be shown.



♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.



Within 1 hour
after dinner or drinking



Immediate measurement
after tea, coffee, smoking



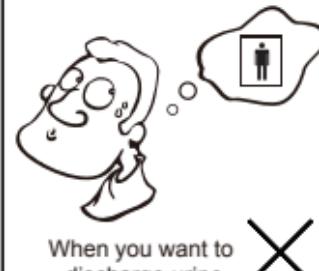
Within 20 minutes
after taking a bath



When talking or
moving your fingers



In a very cold environment



When you want to
discharge urine

♥ Maintenance

To obtain the best performance, please follow the instructions below.



Put in a dry place and avoid the sunshine



Avoid immersing it in the water.
Clean it with a dry cloth in case.



Avoid shaking and collision.



Avoid dusty environment and unstable temperature surrounding



Use the slightly damp cloth to remove the dirt.



Avoid washing the cuff

♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, blood pressure reaches its maximum value, the highest pressure in the cycle is known as systolic pressure. When the heart relaxes between heartbeats, the lowest blood pressure is diastolic pressure.

♥ What is the standard blood pressure classification?

The chart on the right is the standard blood pressure classification published by American Heart Association (AHA).

This chart reflects blood pressure categories defined by American Heart Association.			
Blood Pressure Category	Systolic mmHg (upper#)	and	Diastolic mmHg (lower#)
Normal	less than 120	and	less than 80
Elevated	120-129	and	less than 80
High Blood Pressure (Hypertension) Stage 1	130-139	or	80-89
High Blood Pressure (Hypertension) Stage 2	140 or higher	or	90 or higher
Hypertensive Crisis (Consult your doctor immediately)	Higher than 180	and/or	Higher than 120



CAUTION

Please consult a physician if your measuring result falls outside the range.
Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

♥ Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the device is measuring systolic pressure and diastolic pressure. During each measurement, blood pressure monitor will keep a record of all the pulse intervals and calculate the average value of them. If there are two or more pulse intervals , the difference between each interval and the average is more than the average value of $\pm 25\%$, or there are four or more pulse intervals ,the difference between each interval and the average is more than the average value of $\pm 15\%$, then the irregular heartbeat symbol will appear on the display with the measurement result.



The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

♥ Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.
- 2.If the person takes medicine, the pressure will vary more.
- 3.Wait at least 3 minutes for another measurement.



♥ Why do I get a different blood pressure at home compared to the hospital?

The blood pressure is different even throughout the day due to weather, emotion, exercise etc, Also, there is the "white coat" effect, which means blood pressure usually increases in clinical settings.

♥ Is the result the same if measuring on the right wrist?

It is ok for both wrists, but there will be some different results for different people. We suggest you measure the same wrist every time.



What you need to pay attention to when you measure your blood pressure at home:

- If the cuff is tied properly.
- If the cuff is too tight or too loose.
- If the cuff is tied on the wrist.
- If you feel anxious.
- Taking 2-3 deep breaths before beginning will be better for measuring.
- Advice: Relax yourself for 4-5 minutes until you calm down.

This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the product is not operating as you think it should, check here before arranging for servicing.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display is dim or will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
Low batteries	 +Lo Show on the display	Batteries are low.	Replace with new batteries
Error message	E 01 shows	The cuff is not secure or very tight.	Refasten the cuff and then measure again.
	E 02 shows	The monitor detected motion, while measuring.	Relax for a moment and then measure again.
	E 03 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E 04 shows	Can't calculate blood pressure	Relax for a moment and then measure again.
	E 12 shows	Data communication has failed	Make sure that phone's Bluetooth is on or within the distance range

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
Error message	EExx,shows on the display.	A calibration error occurred. (XX can be some digital symbol,such as 01,02,etc., if this similar situation appear, all belong to calibration error.)	Retake the measurement.If the problem persists,contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions.
Warning message	out shows	Out of measurement range	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician.

Power supply	Battery powered mode: 2*AAA batteries
Display mode	Digital LCD V.A.45mmx33mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg(0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Accuracy	Pressure:5°C-40°C within±3mmHg(0.4kPa) Pulse value:±5%
Working condition	A temperature range of :+5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of : 700 hPa to 1060 hPa
Storage & transportation condition	Temperature:-20°C to +60°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the wrist	About 13.5cm-21.5cm
Weight	Approx.100g(Excluding the batteries)
External dimensions	Approx.86mm×66mm×22mm(Excluding the cuff)
Attachment	2*AAA batteries,user manual

Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Device Classification	Internally Powered ME Equipment
IP Classification	IP22: The first number 2: Protected against solid foreign objects of 12.5mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure tilted up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical.
Software Version	A01

WARNING: No modification of this equipment is allowed.

♥ Contact Information

For more information about our products or online support, please visit www.zewa.com. To contact our customer service, please call 888-993-3592 or support@zewa.com.

Manufactured for Zewa, Inc.
12960 Commerce Lakes Drive#29
Fort Myers, FL 33913 USA
www.zewa.com
Toll Free Customer Service:
1-888-993-3592
warranty@zewa.com

♥ FCC Statement

FCC ID: OU9TMB159

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

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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

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

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

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

♥ Complied Standards List

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labeling	EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements
User manual	EN 1041:2008 +A1:2013 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015/ IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type

Clinical investigation	EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems IEC 80601-2-30:2009+A1:2013 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

♥ EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments

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 equipment WS-380, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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 application
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not application

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, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Not application	Not application
Surge IEC61000-4-5	Not application	Not application
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not application	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	Not application	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 U _T 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	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27	
450	430-470	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28	
710	704-787	LTE Band 13,17	Pulse modulation b) 217Hz	0.2	0.3	9	
745							
780	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28	
810							
870							
930							

	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	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
	5500						
	5785						