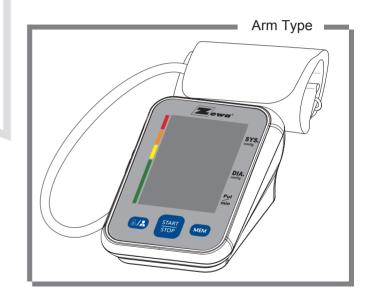


User Manual

Blood Pressure Monitor

UAM-880



- Thank you for purchasing a ZEWA Blood Pressure Monitor.
- To use the monitor correctly and safely, please read the manual thoroughly.

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General Description

Thank you for selecting ZEWA arm type blood pressure Monitor (UAM-880). The monitor features blood pressure measurement, pulse rate measurement and the result storage.

Readings taken by the UAM-880 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:

- 80*60mm Digital LCD display
- · Maximum 60 records per each user
- · Measuring during inflation technology

Indications for Use

The ZEWA Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate with an arm circumference ranging from 22cm to 42cm(about 8%-16½"). 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 .

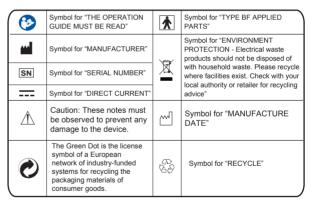
2. The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators.

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 deter- mine 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 components. They are the requirement of standard and using.



INTRODUCTION

- 🕂 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 arm 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 was 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.

* Don't kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.

* When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: connection tubing kinking too frequent and consecutive multiple measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.

* 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.

*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 arm 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.

- \land caution

* 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 arm 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 42.8 $\rm C$ while the environmental temperature is 40 $\rm C$.

* The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.

* Warning: No servicing/maintenance while the ME equipment is in use.

* The patient is an intended operator.

* The patient can measure transmit data and charge power 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 sensization or irritation reaction.

* Adaptor is specified as a part of ME EQUIPMENT.

* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press any button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.

* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures reaches 40 kPa (300 mmHg), detach the cuff from the arm and press any 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 servious 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).

* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.

* Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions,etc., to assist to service personnel in parts repair.

* The plug/adapter plug pins insulates the device from the main supply. Do not position the device in a position where it is difficult to disconnect from the supply mains to safely terminate operation of ME equipment.

* The operator shall not touch output of batteries /adapter and the patient simultaneously.

* 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 informatic particular the ACCONTRACTOR DOCUMENTS.

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 partes 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.

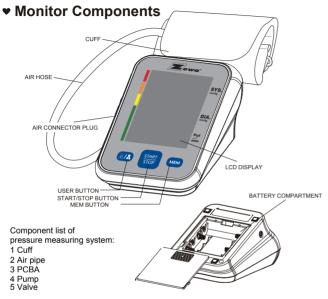
* Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

LCD Display Signal



SYMBOL	DESCRIPTION	EXPLANATION			
SYS.	Systolic blood pressure	High blood pressure			
DIA.	Diastolic blood pressure	Low blood pressure			
Pul min	Pulse display	Pulse in beats per minute			
м р 88/88 рм	Current Time	Time(year:month:day:hour:minute)			
AVG.3	Average value	The average value of lastest 3 groups value blood pressure			
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)			
L0+ 📼	Low battery indicator	Batteries are running low and need to be replaced			
	Irregular heartbeat Detection	Blood pressure monitor is detecting an irregular heartbeat during measurement.			
•	Blood pressure level indicator	Indicate the blood pressure level			
•	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.			
*	User 1	Start measurement, save and transmit the measuring results for User 1			
8	User 2	Start measurement,save and transmit the measuring results for User 2			
E))	Motion indicator	Motion may result in an inaccurate measurement			
	Data pending to transmit	Measurement data stored in the equipment			
8	Bluetooth icon	The Bluetooth icon blinks when the Bluetooth is working			

INTRODUCTION



♥ List

1. Blood Pressure Monitor (UAM-880)



4. User manual

 Cuff (22~42cm) (Type BF applied part)



5.Carry bag



3. 4*AA Batteries

Carry bag



- **1**.Battery powered mode: 6VDC 4*AA batteries
- 2.AC adaptor powered mode: 6V ----1A (Not included) (Please use the AC adaptor which

authorized by the manufacturer!) Right picture is the hole for power adaptor.



→ ▲ CAUTION ·

In order to get the best effect and protect your monitor, please use the the right batteries and special power adapter which complies with local safety standard.

Installing and Replacing the Batteries

- 1. Slide off the battery cover.
- Install the batteries by matching the correct polarity, as shown.
- 3. Replace the cover.

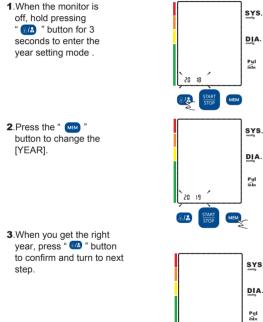
Replace the batteries whenever the below happens

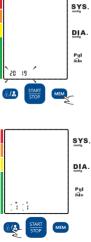
- •The LO + 🕞 shows
- •The display dims
- The display does not light up

- 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.

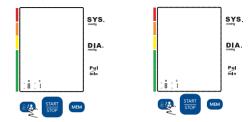
Setting Date and Time

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. (year :2018-2058 time:12 H)

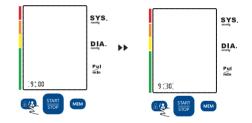




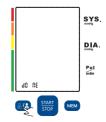
4.Repeat step 2 and 3 to set the [MONTH] and [DAY].



5. Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].

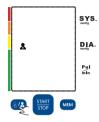


6.After the [MINUTE] is set, the LCD will display "donE" first, then display all the settings you have done and then turn off.



Select the User

1.When the monitor is off , press the " " button shortly to enter user setting mode.



 ${\bf 2}.$ Then press " $\textcircled{\mbox{\scriptsize MS}}$ " button again, select the user ID between user 1 and user 2 .

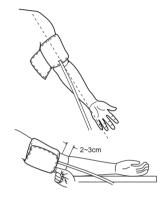


3. After selecting the suitable user ID, press " start the measurement.



♥ Tie the Cuff

- Remove all jewelry, such as watches and bracelets from your left arm. Note: If your doctor has diagnosed you with poor circulation in your left arm, use your right arm.
- Roll or push up your sleeve to expose the skin. Make sure your sleeve is not too tight.
- 3. Hold your arm with your palm facing up and tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger. Or position the artery mark φ over the main artery (on the inside of your arm). Note: Locate the main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.
- The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.
- 5. Sit comfortably with your tested arm 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.
- 6. Helpful tips for Patients, especially for Patients with Hypertension:
- · Rest for 5 minutes before first measurement.
- 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.
- Please sit comfortably. Do not cross your legs and keep your feet flat 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 arm, or as directed by a physician.





MEASUREMENT

♥ Start the Measurement



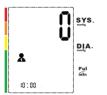
LCD display



Inflating and measuring.



Adjust the zero point .



Display and save the results.



2. This device will proceed to data transmission after measurement. The Bluetooth symbol blinks on the LCD indicates data is transmitting.



3.If the data is successfully transmitted, the Bluetooth symbol will light up, and the **g** will disappear.If the data transmission fails, the device will turn off.

 Image: System

 Image: System

4.Press "

" button to power off, otherwise it will turn off within 1 minute.

MEASUREMENT

Tips:

- A. You can press " stop " button at any time to stop measuring during the process of measurement.
- B. Maximum 60 records are both for USER 1 and USER 2.
- C. 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".

Bluetooth Module No.: LS51802 RF Frequency Range: 2.402 - 2.480 GHz Output Power Range: -6dBm -4dBm Supply Voltage: 1.8V - 3.6V Transmitting Distance: 1-10 meters

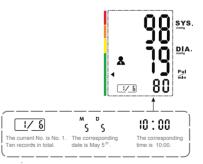
- Interference may occur in the vicinity of equipment marked with the following symbol (a). And UAM-880 may interfering vicinity electrical equipment.
- Sensitive people, including pregnant women pre-eclamptic and those who implanted medical electronic instruments, should avoid using the unit whenever 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.
- 2. 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, please press " ⁽¹⁾ button shortly to show the average value of the latest three records. If the records are less than 3 groups, it will display the latest record instead. (Take user 1 for example.)

AVG.3 69

2. Press the " www " button again to rotate the records. The order of the record, date and time will be displayed alternatively.



- $m \Lambda$ 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

You can delete all results of the selected user by following steps below .

1.When device is turned OFF, press the " WEW " button to go into memory mode. Now press the " WEW " button for 3 seconds until the "User ID + dEL ALL" is flashing.

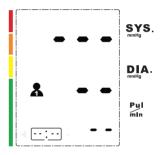


2.Press " we " button to confirm deleting all the memories , the LCD will display "User ID + dEL donE" and the monitor will turn off.



3: To exit the delete mode without deleting any records, press " $\textcircled{\mbox{\m$

4. If there is no record, the below display will be shown



♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.



wait at least 1 hour after dinner or drinking



Wait at least 20 minutes after taking a bath



In a very cold environment



Immediate measurement after tea, coffee, smoking



When talking or moving your fingers



When you want to discharge urine

Maintenance

In order to get the best performance, please follow the instructions below.



Put in a dry place and avoid the sunshine



Avoid intense shaking and collisions



Using wet cloths to remove dirt



Avoid touching water, clean it with a dry cloth in case.



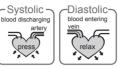
Avoid dusty and unstable temperature environment



Avoid washing the cuff

What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called 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 pressu	re categories defined	by Ameri	can Heart Association.			
Blood Pressure Category Systolic Diastolic mmHg (upper#) Diastolic mmHg (lower#)						
Normal	less than 120	and	less than 80			
Prehypertension	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 value of $\pm 25\%$, or there are four or more pulse intervals, the difference between each interval and the average value of $\pm 15\%$, then the irregular heartbeat symbol will appear on the display with the measurement result.

A CAUTION -

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 arm?

It is ok for both arms, but there will be some different results for different people. We suggest you measure the same arm 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 upper arm. 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.

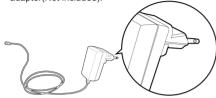
PROBLEM	SYMPTOM	CHECK THIS	REMEDY	
No power	Display will not light up.	Batteries are exhausted. Batteries are inserted incorrectly. AC adaptor is inserted incorrectly.	Replace with new batteries Insert the batteries correctly Insert the AC adaptor tightly	
Low batteries	Display is dim or shows	Batteries are low.	Replace with new batteries	
	E 1 shows	The cuff is not secure.	Refasten the cuff and then measure again.	
	E 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.	
Error message	E 10 or E 11 shows	The monitor detected motion,talking,or the pulse is too poor while measuring.	movement can affect the measurement.Relax for a moment and then measure again.	
	E20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.	
	E21 shows	Measure incorrectly.	Relax for a moment and then measure again.	
	EExx,shows on the display.	A calibration error occurred.	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 "out " shows message		Out of measurement range	the measurement result is out of the measurement range (SYS:60mmHg to 230mmHg; or DIA:40mmHg to 130mmHg;or Pulse: 40-199 pulse/minute)	

Power supply	Battery powered mode: 6VDC 4×AA batteries AC adaptor powered mode: 6V == 1A (Not inicluded) (Please only use the recommended AC adaptor model).
Display mode	Digital LCD V.A.80mm*60mm
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°Cwithin±3mmHg(0.4kPa) Pulse value: ±5%
Normal 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 upper arm	About 22cm~42cm
Weight	Approx.250g(Excluding the batteries)
External dimensions	Approx.102mm*143mm*73mm
Attachment	4×AA batteries,user manual ,Carry bag
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against	IP21 It means the device could protected against
ingress of water	solid foreign objects of 12.5mm and greater, and protect against vertically falling water drops.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
Software Version	A01

WARNING: No modification of this equipment is allowed.

Authorized Component

 please use the ZEWA authorized adapter(Not included).



Adaptor

Type: BLJ06L060100P-U

Input: 100-240V,50-60Hz,0.2Amax Output: 6V === 1000mA

♥ FCC Statement

FCC ID:OU9TMB995-BS

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 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 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
Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
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 62:366-1:2015 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

1)This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

2)* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
 3)Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

4)* Caution: This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Table 1

Guidance and ma	anufacturer's declar	ration – electromagnetic emissions
The device is intended for user of the device should as		netic environment specified below. The customer or the n such an environment.
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that
Harmonic emissions IEC 61000-3-2	Class A	supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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Table 2

sance and manufacturer s	declaration – electrom	agnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.					
IEC 60601 test level	Compliance level	Electromagnetic environment - guidance			
±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be a least 30%.			
power supply lines: ±2 kV input/output lines: ±1 kV	power supply lines: ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.			
line(s) to line(s): ±1 kV line(s) to earth: ±2 kV 100 kHz repetition frequency	line(s) to line(s): ±1 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.			
0%Ur: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0%Ur; 1 cycle and 70%Ur; 25/30 cycles Single phase: at 0° 0% Ur; 300 cycle	$\begin{array}{l} 0\% \; U_{T} \; ; \; 0.5 \; cycle \\ At \; 0^\circ, 45^\circ, 90^\circ, 135^\circ, \\ 180^\circ, 225^\circ, 270^\circ \; and \\ 315^\circ \\ 0\% \; U_{T} \; ; \; 1 \; cycle \\ and \\ 70\% \; U_{T} \; ; \; 25/30 \; cycles \\ Single \; phase: \; at \; 0^\circ \\ 0\% \; U_{T} \; ; \; 300 \; cycle \\ \end{array}$	Mains power quality should be that of a typical commercial or hospital environment.			
30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic field should be at levels characteristi of a typical location in a typical commercial or hospital environment.			
	ded for use in the electromagi ihould assure that it is used in IEC 60601 test level ±8 kV contact ±15 kV air power supply lines: ±2 kV input/output lines: ±1 kV line(s) to line(s): ±1 kV line(s) to line(s): ±2 kV 100 kHz repetition frequency 0%UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°,270° and 315° 70%UT; 1 cycle and 70%UT; 25/30 cycles Single phase: at 0° 0% UT; 300 cycle 30 A/m	ded for use in the electromagnetic environment specifi- thould assure that it is used in such an environment. IEC 60601 test level Compliance level ±8 kV contact ±15 kV air ±8 kV contact ±15 kV air power supply lines: ±2 kV input/output lines: ±1 kV power supply lines: ±2 kV input/output lines: ±1 kV line(s) to line(s): ±1 kV line(s) to earth: ±2 kV 100 kHz repetition frequency line(s) to line(s): ±1 kV inot 0, 45°, 90°, 135°, 180°, 25°, 270° and 315° 0% Ur; 1 cycle and 70% Ur; 25/30 cycles Single phase: at 0° 0% Ur; 300 cycle 0% Ur; 0.5 cycle 0% Ur; 1 cycle and 70% Ur; 25/30 cycles Single phase: at 0° 0% Ur; 300 cycle 30 A/m 30 A/m			

Table 3

	should assure that i			ow. The customer or the		
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance			
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d=0.35\sqrt{P}$;			
Radiated RF IEC 61000-4-3	10V/m, 80% Am at 1kHz	10V/m, 80% Am at 1kHz	80 MHz to 800 MH2: d=1.2√p 800 MH2 to 2.7 GH2: d=2.3√p	where, P is the maximul output power rating of the transmitter in watts (W) according to the transmitter manufacture d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey. 'should be less than the compliance lew in each frequency range Interference may occur the vicinity of equipment marked with the followin symbol: (((•)))		
NOTE 2 These absorption and ref a Field strength telephones ar cannot be pre- fixed RF trans strength in the	lection from structur s from fixed transm d land mobile radic dicted theoretically smitters, an electron e location in which t	t apply in all situations, apply in all situations, and period situations, such as based as a situations, amateur radio, and with accuracy. To nagnetic site survey he device is used to be a such as a situations and situations.	ons. Electromagnetic pro ople. e stations for radio (cell AM and FM radio broad	cast and TV broadcast netic environment due to I. If the measured field RF compliance level		

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Table 4

Recommended separation distances between portable and mobile $\ensuremath{\mathsf{RF}}$ communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz	80 MHz to 800 MHz		
	$d = 3.5\sqrt{P}$	$d = 1.2\sqrt{P}$		
0.01	0.12	0.12		
0.1	0.37	0.38		
1	1.2	1.2		
10	3.8	3.8		
100	12	12		

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 5

			at it is used i	n such an enviro	nt specified belo onment. Modulation b)	Distance (m)	IMMUNITY
IEC61000-4-3 (Test specifications	Frequency (MHz)	(MHz)	,		(W)		TEST LEVEL (V/m)
for ENCLOSURE PORT	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
IMMUNITY to RF wireless communicatio ns equipment)	450	380-390	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
is equipment)	710	704-787	LTE Band	Pulse			
	745		13, 17	modulation b) 217Hz	0.2	0.3	9
	780		17	21/112			
	810	800-960	GSM 800/900.	Pulse	2	0.3	28
	870		TETRA 800, iDEN 820, CDMA 850.	modulation b) 18Hz			
	930		CDMA 850, LTE Band 5				
1: 1: 2 5 5	1720	1990 CDMA 19 GSM 1900 DECT; LTE Band 3,		217Hz	2	0.3	28
	1845						
	1970						
	2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
	5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
	5240						
	5785						
	QUIPMENT o				istance betweer . The 1 m test di		
	shall be mod ative to FM i	ulated usir nodulation	ng a 50% dut , 50% pulse	ty cycle square w modulation at 18	vave signal. 3 Hz may be use	d because wh	ile it does
MANAGEMEN	IT, and using ration distan) higher IM ce. Minimu	MUNITY TĚ: Im separatio	ST LEVELS that	paration distanc are appropriate iigher IMMUNIT	for the reduce	d