Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

MISURATORE DI PRESSIONE GIMA BLUETOOTH
GIMA BLUETOOTH B.P.MONITOR
TENSIOMÈTRE BLUETOOTH GIMA
MEDIDOR DE PRESIÓN DEL BLUETOOTH DEL GIMA

REF **32916 / LS808-BS**

Guangdong Transtek Medical Electronics Co., Ltd.
Zone A, No.105, Dongli Road,
Torch Development District,
Zhongshan, 528437, Guangdong, China
Made in China

EC REP MDSS - Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, Germany

CE 0123

M32916-M-Rev.0-07.20

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INTRODUCTION

General Description

Thank you for selecting Gima arm type blood pressure monitor (LS808-BS). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.
Readings taken by the LS808-BS 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:
- 86.1mm×24mm Digital LCD display
- Measure-during-inflating Technology
- Up to 60 pieces of record stored per each user

Indications for Use

The Gima Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22cm to 42cm (about 8¾˝-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 pressure” equivalent to the atmoshperic pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also 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.

	Caution: read instructions (warnings) carefully		Authorized representative in the European community		Medical Device complies with Directive 93/42/EEC
	Keep in a cool, dry place		Keep away from sunlight		Serial number
	Product code		Lot number		Direct Current
	Manufacturer		Class II applied		Date of manufacture

	Temperature limit		Follow instructions for use		Type BF applied part
	WEEE disposal		For indoor use only		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.				

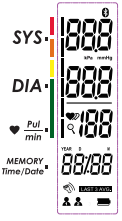
CAUTION

- 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 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 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.
- 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.
- 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 with the adapter 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°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 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, its adaptor, 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.
- 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 pressure 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 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.

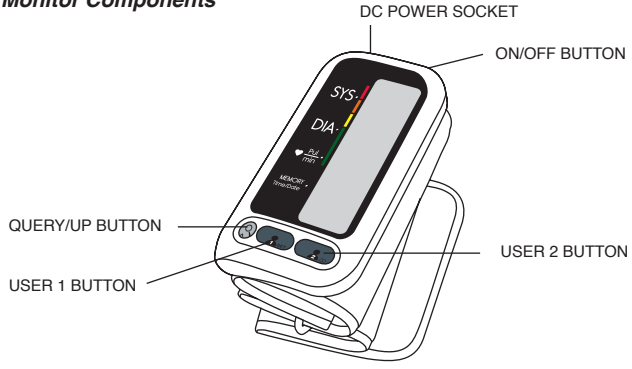
- It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
- Please dispose of ACCESSORIES, detachable 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 insulate 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 Gima. 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 Gima 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 was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

LCD Display Signal

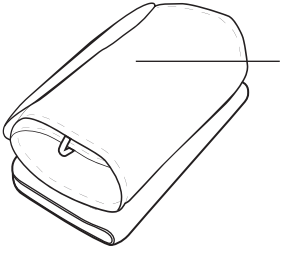


SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic Blood Pressure	High blood pressure
DIA	Diastolic Blood Pressure	Low blood pressure
♥ Pul/min	Pulse display	Pulse in beats per minute
+ Lo	Low Battery	Low battery and please charge the power.
kPa	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
	Bluetooth icon	The bluetooth icon blinks when the blue-tooth is working
LAST 3 AVG.	Average value	The average value of the latest three groups bood pressure value
	Memory Query	Indicate it is in the memory mode and which group of memory it is.
	User 1/User 2	Start measurement for User 1/User 2
YEAR D M	Current time	Year/Month/Day(Hour:Minute)
	Motion indicator	Motion may result in an inaccurate meas-urement.
♥	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
	Blood pressure level indicator	Indicate the blood pressure level
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.

Monitor Components



Component list of
pressure measuring system
1 PCBA
2 Air pipe
3 Pump
4 Valve
5 Cuff

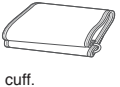


List

1. Blood Pressure Monitor
(LS808-BS)

2. AC Adaptor
(Model: BLJ06L060100P-V)

3. User Manual

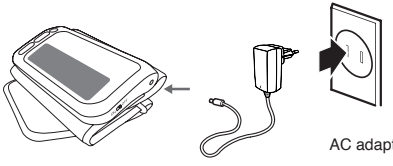


4. Cuff (22cm-42cm)
(Type BF Applied Part)
(Please use Gima authorized cuff.
The size of the actual cuff please
refer to the label on the attached cuff.)

BEFORE YOU START

Power Supply and Charge Power

1. The battery of LS808-BS is built-in rechargeable li-polymer battery, the battery current is 1000 mAh.
2. Please use the AC adaptor to charge the battery, just like the following picture:



AC adaptor

Charging the power under following circumstances:

- + Lo displays on the LCD
- The LCD display is dim.
- When powering on the monitor, the LCD doesn't light up.

CAUTION

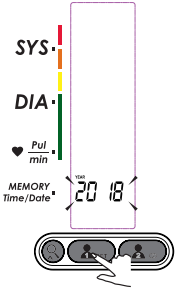
- The battery of LS808-BS is built-in rechargeable lithium-ion battery, please do not disassemble it by the unauthorized maintenance personel.
- Under the normal using, it can charge power about 300 times, if the battery cannot charge the power normally or the blood pressure monitor cannot use normally, please connect with the authorized maintenance personel. If measured three times per day, and the battery is fully charged, it can be used for about 20 days.
- Storge and use the blood pressure monitor at the cool, dry and ventilated environment. Avoid to approach to the fire and the heat source, or it will cause the battery explode.
- Only can use the Gima's authorized AC Adaptor (Model: BLJ06L060100P-V) to charge the power. You cannot use the blood pressure monitor during the process of charging.
- During the process of charging, the blood pressure monitor display . When the charging is finished, please pull the plug in time.
- When charging, shall not touch charging connector and the patient simultaneously.
- Do not attempt to replace your blood pressure monitor's battery. It is built-in and not changeable.
- Only charge the battery in accordance with the user instructions supplied with the blood pressure monitor.
- Avoid charging your blood pressure monitor in extremely high or low temperatures.
- Do not use your blood pressure monitor while you are charging it.
- Do not attempt to disassemble the blood pressure monitor or force open the built-in battery.

- Do not clean the blood pressure monitor when it is being charged. Always unplug the charger first before cleaning the blood pressure monitor.
- Do not dispose of your blood pressure monitor in a fire. The battery could explode causing injury or death.
- Batteries (battery pack or batteries installed) shall not be exposed to excessive heat such as sunshine, fire or the like.

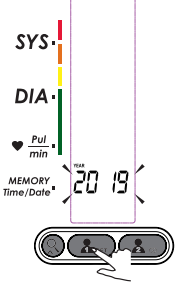
Setting the Time, Date and Unit

To ensure the stored measurement result has correct time record, please set time and unit before device is used.
Before use, switch the button to the “ON” side to turn on the monitor.
Note: If the button is on the “OFF” side, there is no reaction when you press any button.

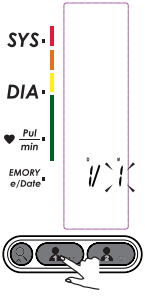
1. When the monitor is on , press and hold
   User 1 button for 3 seconds to enter Year Setting Mode.



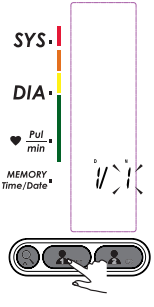
2. As below picture shown , the blinking numeral representing [YEAR].
   Press “Query” button to change the numeral.
   Each press will increase the numeral
   by one in a cycling manner.

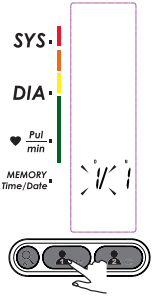


3. Press “User 1” button again to confirm [YEAR].
   Then the numeral representing [MONTH] blinks.

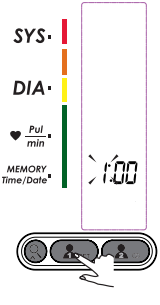


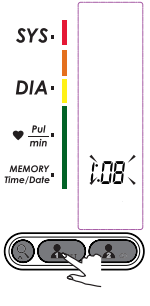
4. Repeat step 2 and 3
   to confirm [MONTH] and [DAY].



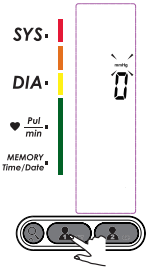


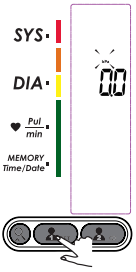
5. Repeat step 2 and 3
   to confirm [HOUR] and [MINUTE].



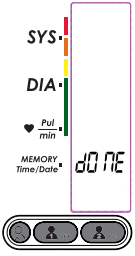


6. Repeat step 2 and 3 to confirm unit.



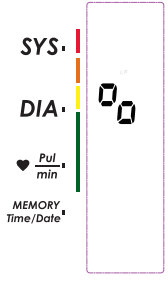


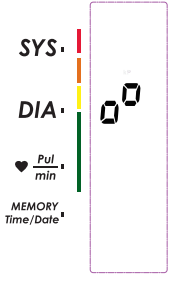
7. After confirming the [UNIT], the LCD will display “dONE” then the monitor will shut off.



Pair-up the Blood Pressure Monitor with Your Device

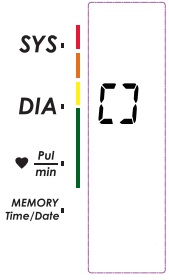
1. Turn on Bluetooth and the app. Make sure both are ON when pair-up is proceeding.
2. In the search device interface, please select the device to pair up.
3. When the monitor is OFF, press and hold the User 2 button to start pair-up. The symbol 0 0 and 0 0 will be shown on the LCD alternatively, indicating pair-up is proceeding.





4. Then please select the user ID you want to connect with your smartphone on the app to continute the pair-up.

If SUCCEED, symbol C
will be shown on the LCD.



If FAIL , symbol E1
will be shown on the LCD.

4. The monitor will shut off after Pair-up process is complete.

Bluetooth Module No.: LS51802
RF Frequency Range: 2402 MHz to 2480 MHz
Output Power Range: ≤0 dBm
Supply Voltage: 1.8-3.6 V
Transmitting Distance: 10 meters

List of compatible devices:
For iOS devices:
The operating system must be iOS 8 or more, such as iPhone 4S, iPhone 5/5C/5S, iPhone 6/6 Plus and so on.
For Android devices:
The operating system must be 4.3 or more.

⚠ CAUTION

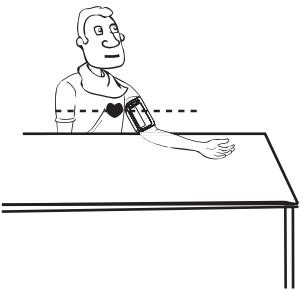
- Interference may occur in the vicinity of equipment marked with the following symbol . And LS808-BS may interfering vicinity electrical equipment.
- Sensitive people, including pregnant women pre-eclamptic and those who implanted medical electronic instruments, should avoid using the unit whenever 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?

1. 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.

Tie the Cuff

1. Remove all accessories (watch, bracelet, etc.) from your arm. If your physician has diagnosed you with poor circulation in your arm, use the other one.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your arm with your palm facing up.
4. Position the edge of the cuff about 2cm~3cm from elbow.
5. Fasten the cuff around your arm, 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 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.
7. 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.



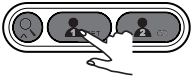
MEASUREMENT

Start Measurement

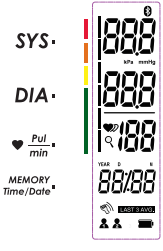
When the monitor is off, press User 1 button to turn on the monitor and it will finish the whole measurement, and then save the measure data .
(Take User 1 for example.)

(Note: Select the same user on your app and BPM to take the measurement, or the measurement data won't be transmitted to the app.)

1. When the monitor is off, press the User 1 button to turn on the monitor.



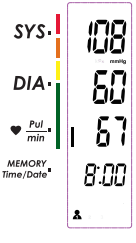
LCD display



Adjust to zero point.

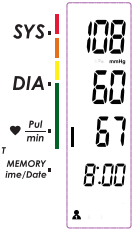
Inflating and measuring.

Display and save the results.
The data transmission will proceed.



If the data transmission succeeds, the Bluetooth symbol will appear then the device will turn off.

If the data transmission fails, the Bluetooth symbol will not appear then the device will turn off.

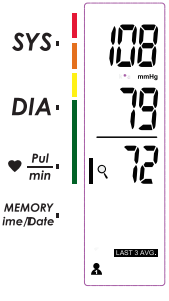


Tips:
A. Maximum 60 records are both for user 1 and user 2.

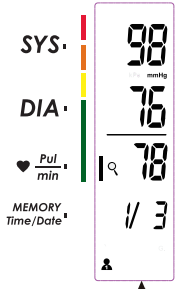
DATA MANAGEMENT

Recall the Records

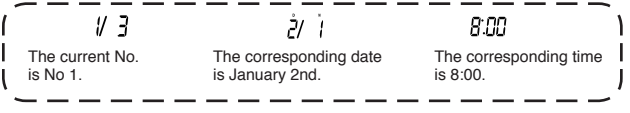
1. When the monitor is off, please press the “Query” button to show the average value of the latest three records. If the records are less than three groups,it will display the latest record first. (Take User 1 for example.)



2. Press the “Query” button again to get the record you want.



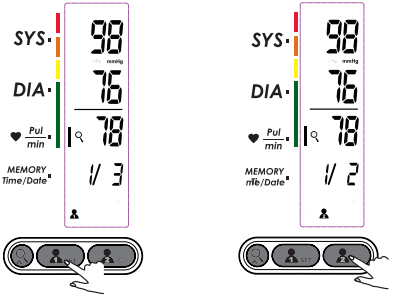
The date and time of the record will be shown alternately.



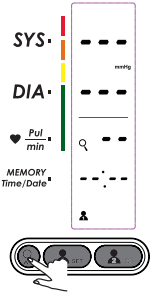
⚠ CAUTION

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.

3. When in the User 1 memory mode, press the User 1 button to turn off the device, or press User 2 button to enter in User 2 memory mode.



4. If there is no record, press “Query” button, the below display will be shown.

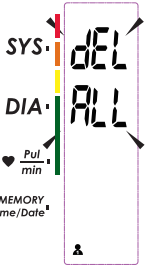


CAUTION

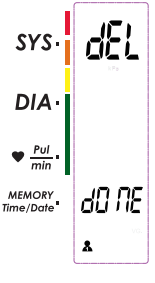
The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

Delete the Records

1. Hold pressing “Query” button for 3 seconds when the monitor is in the memory recall mode , the “dEL ALL+User ID” will flash on the display.



2. Press “Query” to confirm deleting and “dEL donE+User ID” will be shown then the monitor will turn off.



Note: To exit out the delete mode, please press “User 1” button or “User 2 ” button before you press the “Query” button. If there is no operation within 1 minute, the device will turn off.

INFORMATION FOR USER

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

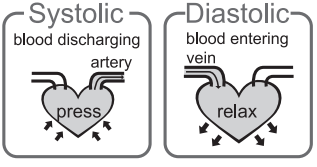
Maintenance

To obtain the best performance, please follow 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 intense shaking and collisions.	 Avoid dusty environment and unstable temperature surrounding
 Use the slightly damp cloth to remove the dirt.	 Avoid washing the cuff

ABOUT BLOOD PRESSURE

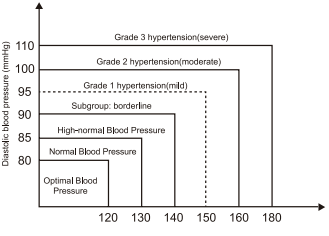
What are systolic pressure and diastolic pressure?

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 blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:



⚠ CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

Level / Blood Pressure (mm Hg)	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS	<120	120-129	130-139	140-159	160-179	≥180
DIA	<80	80-84	85-89	90-99	100-109	≥110

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 ±25%, or there are four or more pulse intervals ,the difference between each interval and the average is more than the average value of ±15%, then the irregular heartbeat symbol will appear on the display with the measurement result.

⚠ 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.

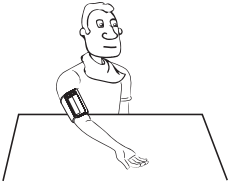
Why do I get a different blood pressure at home compared to the hospital?

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.

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.

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.



TROUBLESHOOTING

This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products 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.	Power is exhausted.	Charge the power
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Display is dim or shows + Lo	Power is low.	Charge the power
Error message	E1 shows	Bluetooth pairing timeout	Make sure that phone's Bluetooth and APP is on and measure again.
	E 3 shows	The cuff is not secure.	Readjust the cuff and relax for a moment and then measure again.
	E 10 or E 11 shows	The monitor detected motion,talking or the pulse is too poor while measuring.	Relax for a moment and then measure again.
	E 20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E 21 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	EEx,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 message	out shows	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)

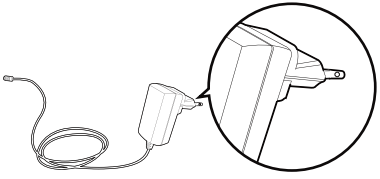
SPECIFICATIONS

Power supply	3.7V 1000mAH Built-in rechargeable li-polymer battery, 6V ⎓ 1A AC Adaptor
Display mode	Digital LCD display V.A.= 86.1mm(L) x24mm(W)
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%
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 arm	About 22cm-42cm
Weight	Approx.284g
External dimensions	Approx.130.9mm×73mm×29.4mm
Attachment	AC Adaptor, user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	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 titled up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is titled at any angle up to 15° on either side of the vertical
Software version	A01
Device classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor charged Mode: Class II ME Equipment

WARNING: No modification of this equipment is allowed.

ATHORIZED COMPONENT

1. Please use the Gima authorized adaptor



Adaptor
Type: BLJ06L060100P-V
Output: 100-240V 50-60Hz,0.2Amax
Input: 6V ⎓ 1000mA

Contact Information

Manufactured by: Guangdong Transtek Medical Electronics Co., Ltd.
Company: Guangdong Transtek Medical Electronics Co., Ltd.
Address: Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China

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 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 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 LS808-BS , 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	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

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	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT; 1 cycle and 70% UT; 25/30 cycles; Single phase: at 0°. 0% UT; 250/300 cycle	0% UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT; 1 cycle and 70% UT; 25/30 cycles; Single phase: at 0°. 0% UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz
NOTE UT is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
	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						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 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						

Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.