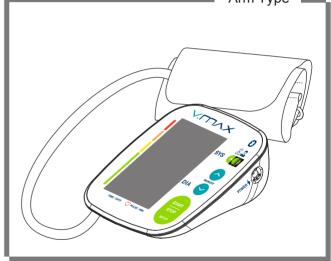


User Manual

Blood Pressure Monitor V.MAX-MX707 Model No: TMB-1490-BS

Arm Type



Thank you very much for selecting V.max-MX707 Blood Pressure Monitor TMB-1490-BS.

Please read the user's manual carefully and thoroughly so as to ensure the safe usage of this product. Keep the manual well for further reference in case you have problems.



- **(** € 0123
 - Guangdong Transtek Medical Electronics Co., Ltd. Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
- EC REP MDSS Medical Device Safety Service GmbH Schiffgraben 41, 30175 Hannover, Germany

Table of Contents

INTRODUCTION
BEFORE YOU START
MEASUREMENT
DATA MANAGEMENT
INFORMATION FOR USER
ABOUT BLOOD PRESSURE
TROUBLESHOOTING 22 SPECIFICATIONS 23 AUTHORIZED COMPONENT 24 CONTACT INFORMATION 24 COMPLIED STANDARDS LIST 25 EMC GUIDANCE 26

INTRODUCTION

♥ General Description

Thank you for selecting V.MAX-MX707 upper arm type blood pressure monitor (Model No: TMB-1490-BS). The monitor features blood pressure measurement, pulse rate measurement and the result storage.

Readings taken by the V.MAX-MX707 are equivalent to those obtained by a trained person using cuff and stethoscope -"auscultatory method".

This manual contains important safety and care information.

This manual provides step by step instructions for using the product. Read the manual thoroughly before using the product.

Features:

- · 60.5 mm×92.5 mm Digital LCD display
- Maximum 250 records per user (2 users)
- * 3rd technology: Measuring during inflation

Indications for Use

The V.MAX-MX707 Blood Pressure Monitor is a digital monitor intended to measure blood pressure and heartbeat rate with arm circumference ranging from 22cm to 42cm(about 8¾"-16½").

It is intended for adult indoor use only.

▼ 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 atmospheric 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 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.

(3)	Symbol for "THE OPERATION GUIDE MUST BE READ"	*	Symbol for "TYPE BF APPLIED PARTS"
C € 0123	Symbol for "COMPLIES WITH MDD 93/42/EEC REQUIREMENTS"	\@\	Symbol for "ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of
	Symbol for "MANUFACTURER"	X	with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling
SN	Symbol for "SERIAL NUMBER"		advice"
	Symbol for "DIRECT CURRENT"	EC REP	Symbol for "Authorized Representative in the European Community
٣	Symbol for "MANUFACTURE DATE"	£2)	Symbol for "RECYCLE"
\bigcap	Caution: These notes must be observed to prevent any damage to the device.		

- A 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 by 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.

CAUTION

- * 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 anesthetic, 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 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 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.
- * 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 the START/STOP 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 reach 40 kPa (300 mmHg), detach the cuff from the arm 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.

CAUTION

* 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

cleaning. Dust environment may affect the performance of the unit. Please use the so 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 your LOCAL DEALER for SERVICE. 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 your LOCAL DEALER 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 distance "d" from the equipment. The "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/ authorized by MANUFACTURER. Otherwise, it may cause damage to the unit or danger to the user/patients.

* There is no "luer lock" connectors 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

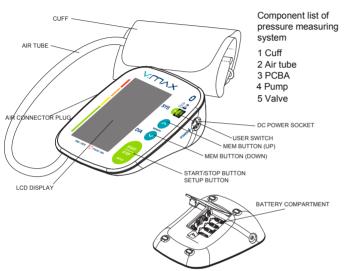


SYMBOL	DESCRIPTION	EXPLANATION		
SYS	Systolic blood pressure	High blood pressure		
DIA	Diastolic blood pressure	Low blood pressure		
Pul/min	Pulse display	Pulse in beats per minute		
▼	Deflation symbol	The cuff is deflating.		
888	Memory	Indicate it is in the memory mode and which group of memory it is.		
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)		
lo+⊫	Low battery	Batteries are running low and need to be replaced		
•	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.		
	Blood pressure level indicator	Indicate the blood pressure level		
88 . 88	Current Time	Month/Day/Year, Hour/Minute		
۵	User A	Start measurement, save and transmit the measuring results for User A		
å	User B	Start measurement, save and transmit the measuring results for User B		
•	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.		
AVG The average value		The average value of the latest three records		
*	Bluetooth icon	The Bluetooth icon blinks when the bluetooth is working		

BEFORE YOU START

♥ Monitor Components

INTRODUCTION



♥ I ist

1.Blood Pressure Monitor (TMB-1490-BS)



3. 4×AAA batteries



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



4.User manual

▼ The Choice of Power Supply

1.Battery powered mode: 6VDC 4×AAA batteries

2.AC adaptor powered mode: 6V ==1A (Not included) (Please only use the recommend adaptor model).



↑ CAUTION

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

▼ Installing and Replacing the Batteries

- · Open the battery cover.
- · Install the batteries by matching the correct polarity, as shown.
- · Replace the battery cover.



Replace the batteries whenever the below happen

- •The shows
- •The display is dim.
- The display does not light up

↑ CAUTION:

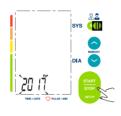
- · Do not use new and used batteries together.
- · Do not use different types of batteries together.
- Do not dispose the batteries in fire. Batteries may explode or leak.
- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not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

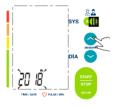
♥ Setting Date and time (SETUP)

It is important to set the time 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 the year: 2017—2057) (time format availabal: 12H/24H)

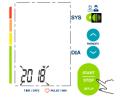
 When the monitor is off, press and hold "START/STOP" button, it will enter the mode for year setting.

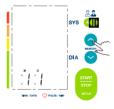
2.Press the " " button or the " " to change the [YEAR]. Each press will increase/decrease the numeral by one in a cycling manner.

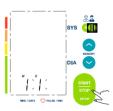




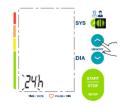
- **3**.When you get the right year, press "START/STOP" button to set down and turn to next step.
- **4**.Repeat steps 2 and 3 to set the [MONTH] and [DAY].

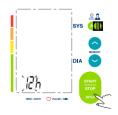






5.Repeat steps 2 and 3 to set the [TIME FORMAT] between 12h and 24h.

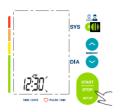




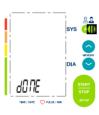
BEFORE YOU START MEASUREMENT

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





7. After the MINUTE is set, the LCD will display "dOnE" first, then will display all the settings you have done and then it will turn off.



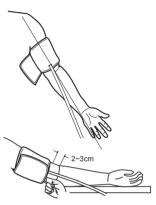
▼ Tie the cuff

- 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.
- 2. 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 \$\Phi\$ 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.
- 4. 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 office and a solution of the patients are the patients and the patients are the patients and the patients are the patients are the patients.

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

 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.





♥ Start the Measurement

Before you start the measurement, Download the "MedM Health" app from "APP Store" or "Play Store", and turn on the Bluetooth.

Install the APP and register an account. Then set your personal information (Gender, Birthday, Height, Weight, Name and so on).

1.Please switch the User button to select between User A and User B. Switch to right to select User A, switch to left to select User B. When the monitor is off, press the "START/STOP button to turn on the monitor, and it will finish the whole measurement, save and transmit the measurement data for the desired user. (Take User A for example.)

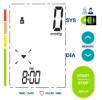
LCD display



Inflating and measuring.



Adjust the zero point.



Display and save the measurement result.



Bluetooth Module No.: LS51802

RF Frequency Range: 2402 MHz to 2480 MHz

Output Power Range: ≤4dBm Supply Voltage: 2V-3.6 V

Transmitting Distance: 10 meters

List of compatible devices:

For iOS devices:

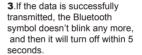
The operating system must be iOS 8 or more, such as iPhone

4S. iPhone 5/5C/5S, iPhone 6/6 Plus and so on.

For Android devices:

The operating system must be 4.3 or more.

2. This device will proceed to data transmission after measurement. The Bluetooth symbol blinks on the LCD indicates data is transmitting. Press the button on the upper left of the app. Select "My Devices", then "Add New". "V.MAX-MX707" will show up, select it and then press "Add to My Devices". Go back to the app's home screen.



If the data transmission fails, it will turn off within 3 minutes.





4. Press the "START/STOP" to power off.

Tips: Maximum 250 records are both for User A and User B.

ACAUTION

- Interference may occur in the vicinity of equipment marked with the following symbol (§2).
 And TMB-1490-BS may interfere with the 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.
- 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 the "MEM", it will display the latest record first when the records are less than three groups. When there are three or more than three groups, it will display the average value of the latest three records first.
- 2. Press the "a" or "a" to get the record you want.







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

The current No. is No 2. The corresponding date is January 6th. The corresponding time is P.M. 10:08.

If you want to look over another user's data, switch the User button to select the desired user. Then you can look over its historical records.

· A 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 (250) is dropped from the list.

♥ Delete the Records

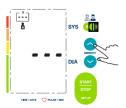
If you did not get the correct measurement, you can delete all results for the selected user by following steps below.

- 1.Hold pressing " " button for 3 seconds when the monitor is in the memory recall mode, "dEL ALL+ USER ID" will be shown on the display.
- 2.Press " or to confirm deleting and "dEL donE + USER ID" will flash on the display then the monitor will turn off.
- 3.If you don't want to delete the records, press "START/STOP" to escape.
- 4. If there is no record, press " > " button, the right display will be shown.









INFORMATION FOR USER INFORMATION FOR USER

▼ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.



♥ 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



Do not attempt to clean the reusable cuff with water and never immerse the cuff in water.

♥ Contraindications

- 1. The device should not be used by any person who may be suspected of, or is pregnant.
- The device is not suitable for use on patients with implanted electrical devices, such as cardiac pacemakers and defibrillators.
- 3. We suggest above-mentioned population measure blood pressure through hosiptal to prevent misdiagnosis caused by inaccurate results.

♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the Systolicheart, the blood pressure reaches its maximum value blood discharging 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.

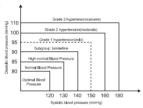




♥ What is the standard blood pressure classification?

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

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.

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heart-beat 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?

- Individual blood pressure varies multiple times throughout the day. 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? your blood pressure at home:

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

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 vou calm down.



TROUBLESHOOTING SPECIFICATIONS

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
	Dianlay will not	Batteries are exhausted.	Replace with new batteries
No power	Display will not light up.	Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Display is dim or show □ + L 0	Batteries are low.	Replace with new batteries
	E 01 shows	The cuff is too tight or too loose.	Refasten the cuff and then measure again.
	E 02 shows	The monitor detected motion while measuring.	Movement can affect the measurement.Relax for a moment and then measure again.
Error message	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	The treatment of the measurement failed.	Relax for a moment and then measure again.
	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 ther measure again. If the problem persists, contact your physician.

$\overline{}$	
Power supply	Battery powered mode: 6VDC 4×AAA batteries AC adaptor powered mode: 6V == 1A (Not included) (Please only use the recommended AC adaptor model).
Display mode	Digital LCD display V.A.60mm × 92mm
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 and cuff)
External dimensions	Approx.140mm×130mm×49.7mm
Attachment	4×AAA batteries,user manual
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.

COMPLIED STANDARDS LIST

♥ Authorized Component

1. please use the VITAX authorized adapter (Not included).



Adapter
Model:BLJ06L060100P-B
Input:AC 100-240V
50/60Hz 0.2A Max
Output: 6V=== 1000mA

♥ Contact Information

For more information about our products, please visit www.vie-max.com. you can get customer service, usual problems and customer download, Vie-max will serve you anytime.

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

Authorized European Representative: Company: MDSS - Medical Device Safety Service GmbH Address: Schiffgraben 41, 30175 Hannover, Germany

International Distributor : VIE MAX scs www.vie-max.com v.max@vie-max.com

Distributor in Lebanon : HOSPISERVICES / Beirut support@hospiservices.com

Phone: +961-9-237 987 Hotline: +961-9-666 909

▼ 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 60601-1:2008/ 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 medic electrical equipment and medical electrical systems used in the hom 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 Requirements and test methods for non-automated measurement lyt EN 1060-3:1997-A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems i IEC 80601-2:30:2013 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: Ter 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 basefety and essential performance - Collateral standard: Usability EN 62:366-1:2015/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-Pat 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!

Guidance and manufacturer's declaration - electromagnetic emissions

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

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.					
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				

Table 2

Guidance and manufacturer's declaration - electromagnetic 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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±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 at least 30%.
Electrical fast transient/burst IEC 61000-4-4	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.
Surge IEC61000-4-5	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.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0%Uτ: 0.5 cycle At 0°, 45°, 90°, 135°, 180°,225°,270° and 315° 0%Uτ; 1 cycle and 70%Uτ; 25/30 cycles Single phase: at 0° 0% Uτ; 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.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

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.

user of the device	snould assure that i	it is used in such ar	n environment.		
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 pa of the device, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d=0.35\sqrt{P}$; $d=1.2\sqrt{P}$		
Radiated RF IEC 61000-4-3	10V/m, 80% Am at 1kHz	10V/m, 80% Am at 1kHz	80 MHz to 800 MHz: d=1.2 \sqrt{P} 800 MHz to 2.7 GHz: d=2.3 \sqrt{P}	where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, 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 level in each frequency range, b Interference may occur in the vicinity of equipment marked with the following symbol:	

NOTE 1 At 80 MHz and 800 MHz, 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.

a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4

Recommended separation distances between portable and mobile 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	50 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2.7 GHz					
	$d = 3.5\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$				
0.01	0.12	0.12	0.23				
0.1	0.38	0.38	0.73				
1	1.2	1.2	2.3				
10	3.8	3.8	7.3				
100	12	12	23				

For transmitters rated at a maximum output power not listed above, the recommended separation distance \mathbf{d} in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where \mathbf{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

Guidance and manufacturer's declaration - electromagnetic 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.

user of the device, should assure that it is used in such an environment.							
Radiated RF IEC61000-4-3 (Test specifications	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	IMMUNITY 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		GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710	704-787	LTE Band	Pulse			9
	745]	13, 17	modulation b) 217Hz	0.2	0.3	9
	780		117	21/11/2			
	810	800-960	GSM 800/900,	Pulse modulation b)	2	0.3	28
	870		TETRA 800, iDEN 820, CDMA 850, LTE Band 5	18Hz			
	930						
	1720	1700- 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	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 b) 217 Hz	2	0.3	28
	5240	5100- 5800	WLAN 802 11	Pulse modulation b)	0.2	0.3	9
	5500	3600	802.11 a/n	217 Hz			
	5785						

NOTE If necessary, to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher limbunity TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be minimum separation distance. will immore calculated using the following equation: $\mathsf{E} = \frac{6}{d} \sqrt{P}$

$$E = \frac{6}{3} \sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.