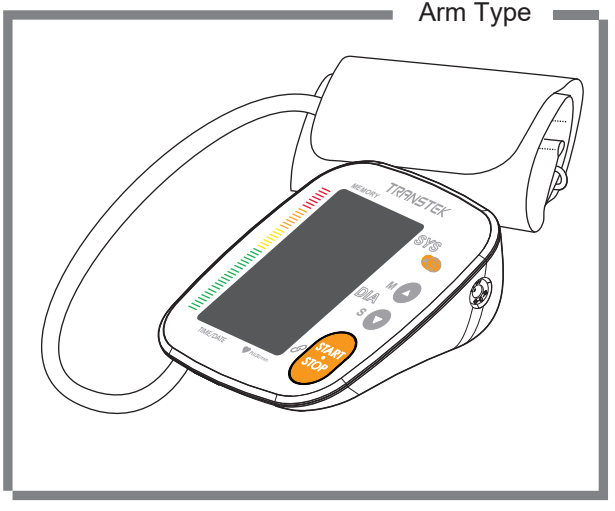
Version: 1.0

TRANSTEK

User Manual

Blood Pressure Monitor

Model: TMB-1490-BHJ



Thank you for selecting Transtek Blood Pressure Monitor. Please read the user manual carefully and thoroughly so as to ensure the safe usage of this product. Keep this manual for further reference in case any issues arise.

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Zhongshan, 528437, Guangdong, China

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♥ General Description

This product features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.

Readings taken by this blood pressure monitor TMB-1490-BHJ is 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 this blood pressure monitor. Read the manual thoroughly before using this product.

Features:

- 60.5 mm × 92.5 mm Digital LCD display
- Maximum storage of 250 records per user
- Up-to-date measuring-during-inflation technology

♥ Indications for Use

This Blood Pressure Monitor TMB-1491-BHJ is a digital monitor intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22 cm to 32 cm (about 8¾″-12½″), 22 cm to 42 cm (about 8¾″-16½″).
It is intended for indoor, adult use only.

♥ Contraindications

1. The device is not suitable for use on the women who are or may be 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 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 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.

	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons , be presented on the medical device itself.		Symbol for “ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”
	Symbol for “SERIAL NUMBER”		Symbol for “Recycle”
	Symbol for “DIRECT CURRENT”		For indoor use only
	Symbol for “MANUFACTURER”		Symbol for “Class II Equipment”
	Symbol for “MANUFACTURE DATE”		

⚠ CAUTION

* This device is intended for adult use in homes only.
* The device is not suitable for use on neonatal patients, pregnant women, patients with implanted, electronical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses.
* The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
* The device is not intended for patient transport outside a healthcare facility.
* The device is not intended for public use.
* This device is intended for no-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not begin or end medical treatment without asking a physician for treatment advice.
* If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.
* Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
* When the device was used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result.
* Don't kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.
* When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: connection tubing kinking too frequent and consecutive multiple measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.
* Warning: Do not apply the cuff over a wound, otherwise it can cause further injury.
* Do not inflate the cuff on the same limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.
* On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure > 300mmHg or constant pressure >15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.
* Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measurement, please avoid compression or restriction of the connection tubing.

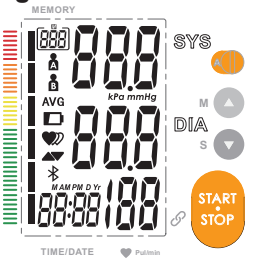
⚠ CAUTION

* The device cannot be used with HF surgical equipment at the same time.
* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2018.
* 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 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, its adapter, 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 sensitization or irritation reaction.
* Adapter 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 reaches 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.
* Do not wash the cuff in a washing machine or dishwasher!

⚠ CAUTION

* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
* Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, etc., to assist to service personnel in parts repair.
* The plug/adapter plug pins insulates the device from the main supply. Do not position the device in a position where it is difficult to disconnect from the supply mains to safely terminate operation of ME equipment.
* The operator shall not touch output of batteries/adapter and the patient simultaneously.
* Cleaning: Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
* The device doesn't need to be calibrated within two years of reliable service.
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Transtek. 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 Transtek 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 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/authorized 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

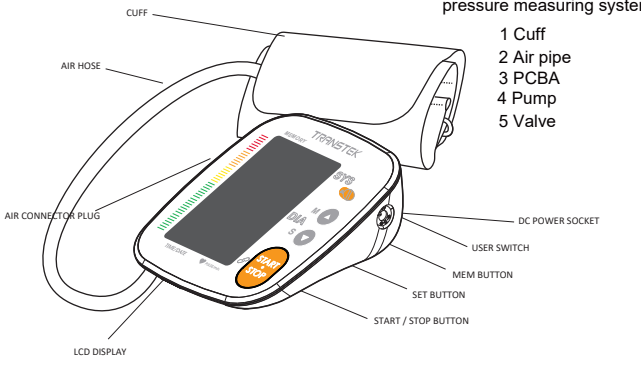


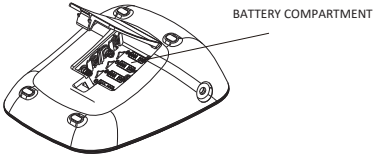
SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	The high pressure measured.
DIA	Diastolic blood pressure	The low pressure measured.
mmHg	mmHg	Measurement Unit of the blood pressure. (1 kPa=7.5 mmHg).
kPa	kPa	Measurement Unit of the blood pressure. (1 mmHg = 0.133 kPa)
Pul/min	Pulse/minute	Measurement Unit of Pulse Rate.
♥	Heartbeat	Heart rate decteted during measurement.
♥	Irregular heartbeat	Irregular heartbeat detected during measurement.
A B	User ID	A appears when the monitor is operated by User A. B appears when the monitor is operated by User B. NOTE: User A and User B, each with 250 memory spaces.
AVG	The average value	The average value of the latest three records.
▼	Deflation symbol	The cuff is deflating.
ᛒ	Bluetooth transfer icon	The bluetooth transfer icon blinks when the bluetooth is working.
+bAt +Lo	Low battery	Batteries are low and need to be replaced.
	Blood pressure level	Indicates the blood pressure level.
	Memory display	Indicate it is in the memory mode and which group of memory it is.
	Current Time	Time and date (year/month/day; hour:minute).

♥ Monitor Components

Component list of pressure measuring system

1 Cuff
2 Air pipe
3 PCBA
4 Pump
5 Valve





♥ List

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

2. Cuff (Type BF applied part)
   22 cm ~ 32 cm
   22 cm ~ 42 cm

3. 4× AAA batteries

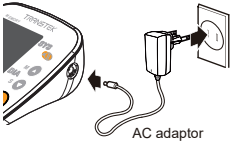
4. AC Adapter BLJ06L060100P-U

5. User manual

♥ The Choice of Power Supply

1. Battery powered mode:
   6V DC 4× AAA batteries
2. AC adapter powered mode: 6V ⎓ 1A
   (Please only use the recommended AC adapter)

   Please unplug the adapter to depart from the using utility power, when you finish the measurement.

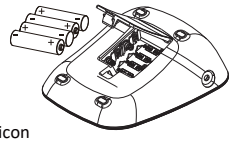


⚠ CAUTION

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 or replace 4x AAA size batteries as indicated in the battery compartment.
- Place back the battery cover.



Any time the battery is low, it will display the icon "bAt Lo"& ▭. It will power off automatically after about 5 seconds.

Low Battery

Replace the batteries if:
- The low battery symbol appears on the display.
- When any button is pressed but nothing is displayed on the screen.
- The display is dim.

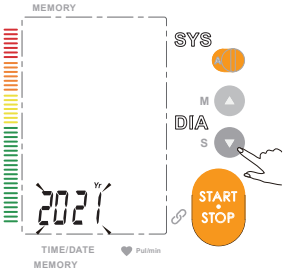
⚠ CAUTION

- 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 dailygarbage.
- Remove the old batteries from the device following your local recycling guidelines.

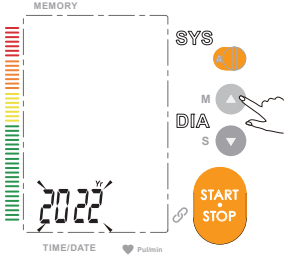
♥ Setting Date and Time

It is important to set the Date and Time 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: 2021—2051, Time format: 12/24H)

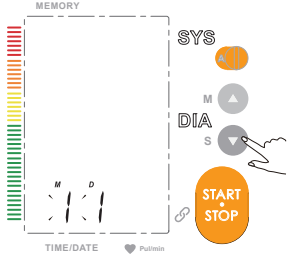
1. When the monitor is off, press "SET" button, it will display the time. Then press and hold "SET " button to enter the mode for year setting.



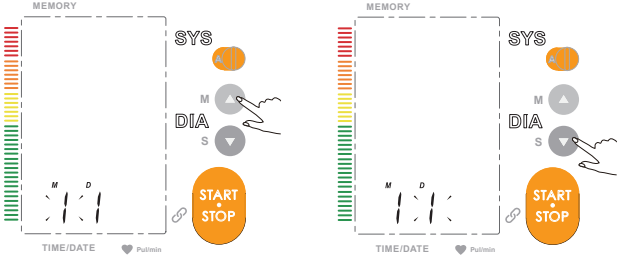
2. Change the [YEAR] by pressing "MEM" button. Each press "MEM" button will increase the number by one in a cycling manner.



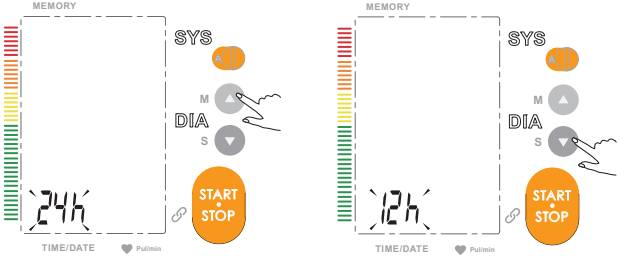
3. When you get the right year, press "SET" button to confirm the entry. The screen will then show a blinking number representing the [MONTH].



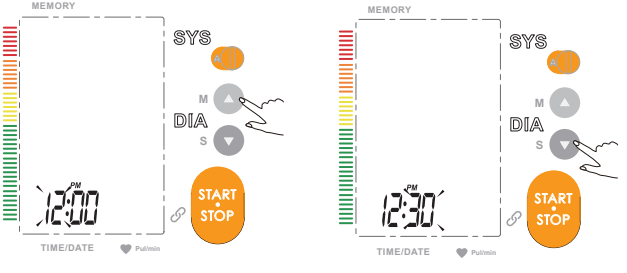
4. Repeat steps 2 and 3 to set the [MONTH] and [DAY].



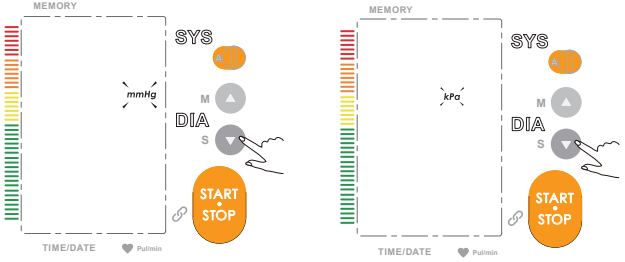
5. Repeat steps 2 and 3 to set the [TIME FORMAT] between 12H and 24H.



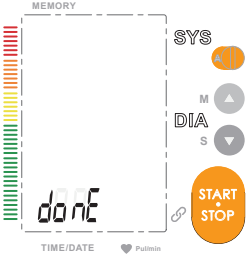
6. Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].



7. Repeat steps 2 and 3 to set the [UNIT].



8. After the unit is set,the LCD will display “donE” first, then display all the settings you have done and then it will turn off.



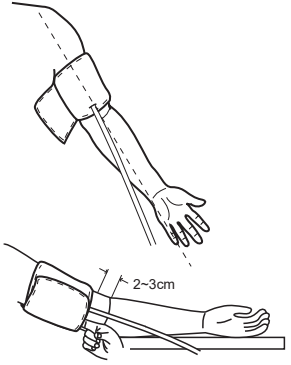
♥ Tie the cuff

1. 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 ϕ over the main artery (on the inside of your arm). Note: Locate the main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.

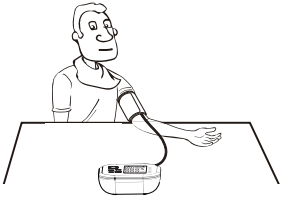
4. The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.



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 measuring.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- Take the measurement in a silent room.
- The patient must relax as much as possible and do not move and talk during the measurement procedure.



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

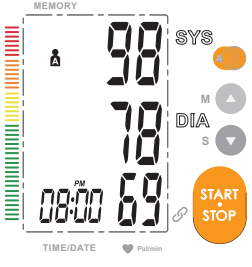
♥ Start the Measurement

Before you start the measurement, download the MedM Health app from APP Store or Google Play, 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).

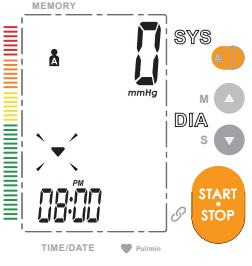
1. Switch the User button to select the user between User A and User B. Switch to right to select User A, switch to left to select User B.

When the monitor is off, press the “START/STOP” button to turn on the monitor, and it will display the latest record and finish the whole measurement,save and transmit the measurement data for the desired user. (Take User A for example.)

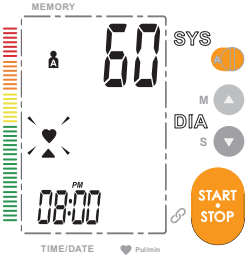
Display the latest record.



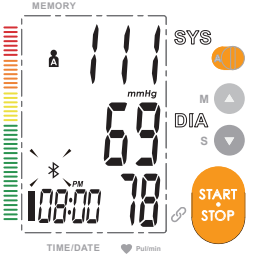
Adjust the zero.



Inflating and measuring.



Display, save and transmit the measurement result.



2. The monitor will save and transmit the measurement result after measurement. (Make sure both Bluetooth and App are ON during the transmission)

If successful, both symbols “ ” will disappear, and then the monitor will power off automatically.

If unsuccessful, the monitor will power off automatically.

Tip 1: Any time if you want to stop the measurement, press “START/ STOP” button.

Tip 2: Both User A and User B can store maximum 250 groups of record. When you pass that limit, every time you take the measurement, the monitor will prompt “FULL” first and the oldest record will drops from the list after the measurement.

List of compatible devices:
For iOS devices:
The operating system must be iOS 13.0 or more.
For Android devices
The operating system must be Android 5.0 or more

⚠CAUTION

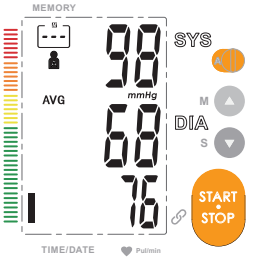
- Interference may occur in the vicinity of equipment marked with the following symbol. And TMB-1490-BHJ may interfer the vicinity electrical equipment.
- Sensitive people, including pregnant women, pre-eclamptic and those who implanted medical electronic instruments, should avoid using the unit whenever 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.
2. To avoid interference, other electronic devices (particularly those with wireless transmission/Transmitter) should be kept at least 1 meter away from the monitor. And BT end so as to obtain quality connection and to lower the RF output range.

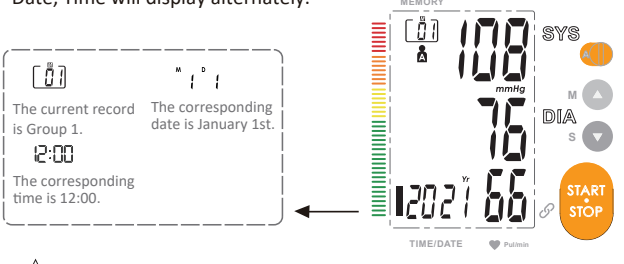
♥ Recall the Records

1. When the monitor is off, press “MEM” button it will display the average value of the latest three records within 30 minutes. When the records are less than three groups within 30 minutes, it will display the latest record.



2. Press "SET" or "MEM" button to query next measurement record. Each press “MEN" or "SET” button will increase or decrease the number by one in a cycling manner.

Date, Time will display alternately.



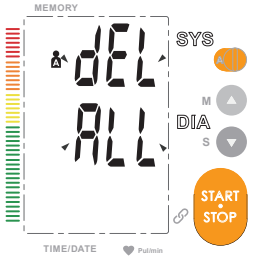
⚠CAUTION

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 (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. (Take User A for example.)

1. When the monitor is in the memory recall mode, press and hold “SET” button, the LCD will display “dEL ALL” + User ID.

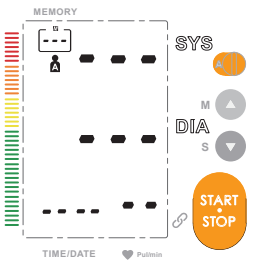


2. Press “SET” button to confirm deletion, the LCD will display “dEL do nE” + User ID.

If you wish to stop clearing the memory, press “START/STOP” button to eascape.

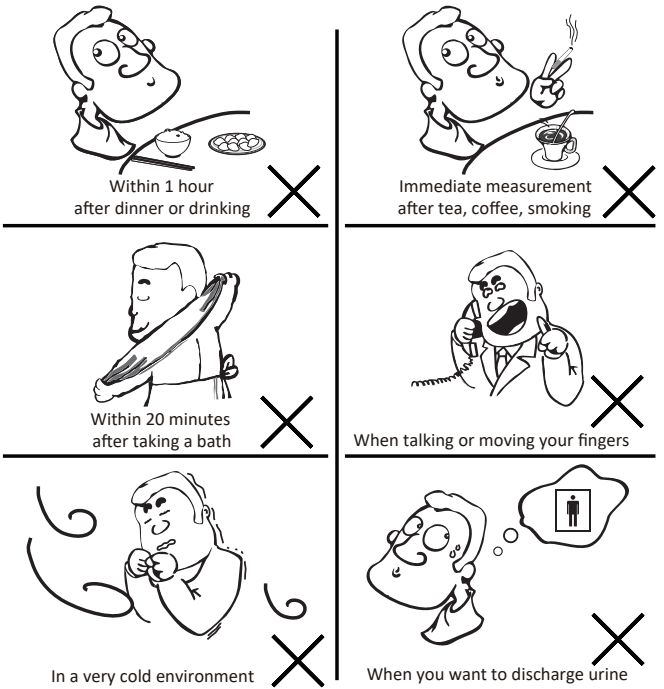
3. Once deleted, your readings cannot be restored. The LCD will display “--” like the picture on the right.

Press “START/STOP” button to turn off the monitor, otherwise it will power off automatically after about 1 minute.



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

Avoid intense shaking and collisions

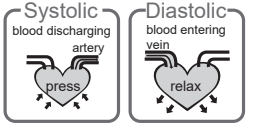
Avoid dusty and unstable temperature environment

Using wet cloths to remove dirt

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

♥ 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.

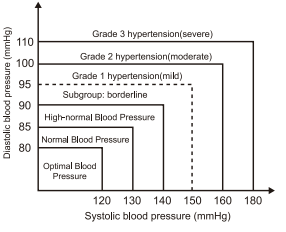


♥ What is the standard blood pressure classification?

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.



Blood Pressure (mmHg) \ Level	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 unit is measuring the systolic and diastolic blood pressure. During each measurement, the monitor records all the pulse intervals and calculate the average; 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%, the irregular heartbeat symbol appears on the display when the measurement results are appeared.

⚠ CAUTION

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?

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 different blood pressure at home compared to the hospital?

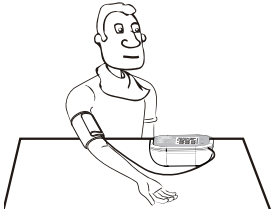
The blood pressure is different even throughout the day due to weather, emotion, exercise etc. Also, there is the "white coat" effect, which means blood pressure usually increases in clinical settings.

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.



If any abnormality arises during use, please check the following points:

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display can not light up.	Batteries are exhausted.	Replace with new batteries.
		Batteries are inserted incorrectly.	Insert the batteries correctly.
		Adapter is inserted incorrectly.	Insert the AC adapter correctly.
High power	H bAt shows	Adapter voltage is higher than 7.5V	Replace with the authorized adapter
Low batteries	Lo bAt & ▭ shows	Batteries are low.	Please replace batteries.
Error message	E 01 shows	The cuff is not wrapped or wrapped incorrectly, or the cuff air plug is loose.	Refasten the cuff and insert air tube plug correctly then measure again.
	E 02 shows	Hand shaking or talking or moving is detected during measuring.	Relax for 5 minutes. and then keep still, measure again.
	E 03 shows	Pulse is not detected during measuring.	Loosen the clothing on the arm and then measure again.
	E 04 shows	The measurement failed.	Relax for 5 minutes and measure again.
	EEx shows	Hardware error (X can be some digital symbol,such as 1, 2, etc.)	Turn off monitor and measure again. If EEx still appears on the display, please contact the retailer or our customer service.
Warning message	"out" shows	Out of measurement range	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician.

NOTE: If the product still does not work, contact Transtek Customer Service. Under no circumstance should you disassemble or attempt to repair the unit by yourself.

SPECIFICATIONS

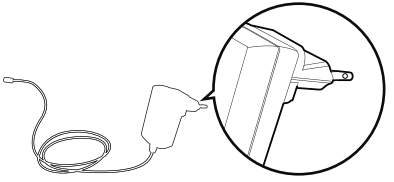
Power supply	Battery powered mode: 6V DC 4× AAA batteries AC adapter powered mode: 6V ⎓ 1A (Please only use the recommended AC adapter).
Display mode	Digital LCD V.A. 60 mm × 92 mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0 mmHg ~ 299 mmHg (0 kPa ~ 39.9 kPa) Measurement pressure: SYS: 60 mmHg ~ 230 mmHg (8.0 kPa ~ 30.7 kPa) DIA: 40 mmHg ~ 130 mmHg (5.3 kPa ~ 17.3 kPa) Pulse value: (40-199) beat/minute
Accuracy	Pressure: 5°C - 40°C within ±3 mmHg (0.4 kPa) 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 50 hPa
Measurement perimeter of the upper arm	About 22 cm to 32 cm (about 8¾″-12½″) or 22 cm to 42 cm (about 8¾″-16½″)
Weight	Approx.230g (Excluding the batteries and cuff)
External dimensions	Approx.140 mm × 130 mm × 49.7 mm
Attachment	4× AAA batteries, user manual, AC adapter
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP20 It means the device could protected against solid foreign objects of 12.5mm and greater, and there is no special protection for water or moisture.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adapter Powered Mode: Class II ME Equipment
Software Version	A01
Bluetooth Module information	Bluetooth Module No.: RF Frequency Range: 2402 MHz to 2480 MHz Output Power Range: ≤-2.5 dBm Supply Voltage: 1.8-3.6 V Transmitting Distance: 10 meters

WARNING: No modification of this equipment is allowed.

AUTHORIZED COMPONENT

♥ Athorized Component

Please use the TRANSTEK authorized adapter.



Adapter
Type: BLJ06L060100P-U
Input: 100-240 V, 50-60 Hz, 0.2A max
Output: 6V ⎓ 1000 mA

♥ Contact Information

For more information about our products, please visit www.transtekcorp.com. You can get customer service, usual problems and customer download, Transtek will serve you anytime.

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

FCC STATEMENT

♥ FCC Statement

FCC ID: OU9TMB1490BH

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

FCC Radiation Exposure Statement:

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

COMPLIED STANDARDS LIST

♥ Complied Standards List

Risk management	EN ISO 14971:2019 / ISO 14971:2019 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+A12:2014 / 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 IEC80601-2-30:2018 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	EN ISO 81060-2:2019/ISO 81060-2:2018, 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 10993-1:2018 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 be near the 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 TMB-1490-BHJ 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, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not Applicable 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 Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 250 / 300 cycle	0% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 250 / 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz
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 U_T is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communicati-ons equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM ± 5k Hz deviation 1 kHz sine	2	0.3	28	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	745							
	780							
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation 217 Hz	2	0.3	28	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	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
	5500							
	5785							