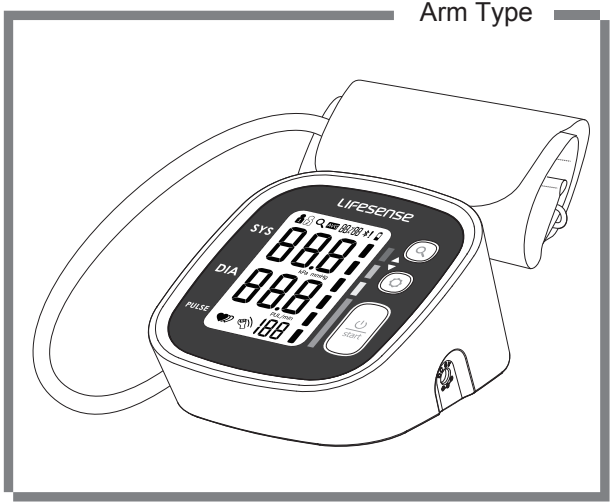
version:1.0

TRANSTEK

User Manual

Blood Pressure Monitor TMB-1597-BN

Arm Type



- Thank you very much for selecting TRANSTEK Blood Pressure Monitor TMB-1597-BN.
- Please do read the user manual carefully and thoroughtly so as to ensure the safe usage of this product, and keep the manual well for further reference in case you have problems.

Bluetooth®

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CATALOGUE

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♥ General Description

Thank you for selecting TRANSTEK arm type blood pressure monitor (TMB-1597-BN). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.

Readings taken by the TMB-1597-BN are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step by step instructions for using the product.

Read the manual thoroughly before using the product.

Features:

- 73mm×49 mm Blue LCD display with white backlight
- Maximum 60 records per each user
- 3rd technonoly: Measuring during inflation

♥ Indications for Use

The Transtek Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22 cm to 32 cm (about 8¾″-12½″) or 22cm to 42cm(about 8¾″-16½″).
It is intended for adult indoor use only.

♥ Contraindications

This device is contraindicated for any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator.
This blood pressure monitor is not intended to be a diagnostic device.
Contact your physician if hypertensive values are indicated.

♥ 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 air 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.

The device also compares the longest and the shortest time intervals of detected pulse waves to mean time interval then calculates standard deviation. The device will display a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.

♥ 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”
	Symbol for “MANUFACTURER”		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”
SN	Symbol for “SERIAL NUMBER”		
	Symbol for “DIRECT CURRENT”		
	Symbol for “MANUFACTURE DATE”		For indoor use only
F1	T1A/250V Φ3.6*10CCC		Symbol for “Class II Equipment”
Bluetooth	The Bluetooth Combination Mark		Caution: These notes must be observed to prevent any damage to the device.
	Symbol for “Including RF transmitter”		

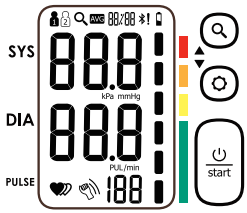
⚠ CAUTION

* This device is intended for adult use only. It is not intended for use with neonatal patients, pregnant or pre-eclamptic patients.
* 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.
* 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.
* If the cuff pressure exceeds 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures exceeds 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
* 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.
* The operator shall not touch output of batteries /adapter and the patient simultaneously.
* To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* The user must check that the equipment functions safely and see that it is in proper working condition before being used.
* 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.
* Manufacturer will make available on request circuit diagrams, component parts list etc.
* 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.
* 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.
* During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensization or irritation reaction.
* Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
* The device doesn't need to be calibrated within two years of reliable service.
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.

⚠ CAUTION

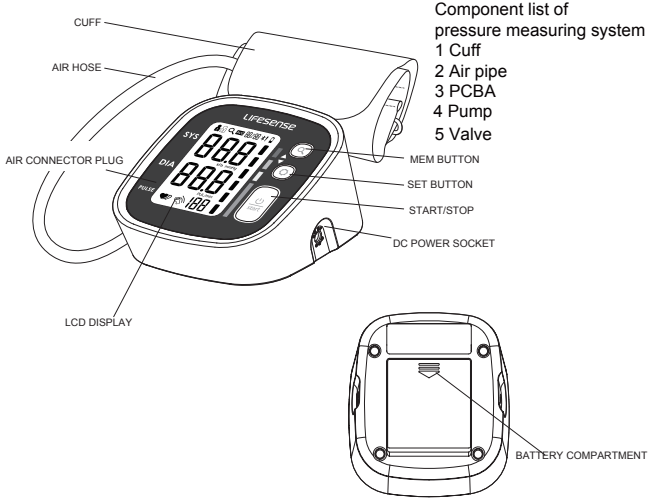
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Transtek. Don't open or repair the device by yourself.
* Please report to Transtek if any unexpected operation or events occur.
* Please use the soft cloth to clean the whole unit. Don't use any abrasive or volatile cleaners.
* 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 battery under normal circumstances and maintain the device and its accessories according to the user manual.
* Adaptor is specified as a part of ME EQUIPMENT.
* 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.
* Before every use, check the device, do not use the device or an electrode if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.
* Keep unit out of the reach of young children / pets to avoid inhalation or swallowing of small parts. The cord/tube can cause strangulation.
* 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.
* 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.
* Warning: Be careful to regarding the effect of blood flow interference and resulting harmful injury to the patient caused by continuous cuff pressure due to connection tubing.
*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 samb 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.
* Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measurement, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.
* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.
* To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
*This device 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.
* Do not wash the cuff in a washing machine or dishwasher!
* 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).
* 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.
* This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
• Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is caculated by the MANUFACTURER from the 800 MHz to 2.5 GHz column of Table 6 of IEC 60601-1-2:2007,as appropriate.

♥ 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.
	Memory	Indicate it is in the memory mode and which group of memory it is.
kPa	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
Lo+	Low battery	Batteries are 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	Year/Month/Day, Hour/Minute
♥	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
	User 1	Start measurement,save and transmit the measuring results for User 1
2	User 2	Start measurement, save and transmit the measuring results for User 2
	Motion indicator	Motion may result in an inaccurate measurement
AVG	Average value	The average value of blood pressure
	Bluetooth icon	Indicate the Bluetooth is working
!	Data storage	Indicate the data is waiting to be transmitted

♥ 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-1597-BN)

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

(Please use TRANSTEK authorized cuff. The size of the actual cuff please refer to the label on the attached cuff.)

3. 4×AA alkaline batteries

4.User manual

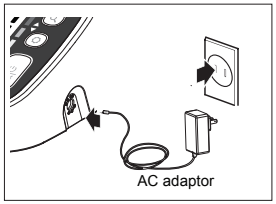
5. AC Adaptor (KH0601000UW!)

♥ The Choice of Power Supply

1.Battery powered mode:
6VDC 4×AA alkaline batteries

2.AC adaptor powered mode:
6V ⎓ 1A
(Please only use the recommended AC adaptor model).

Please unplug the adaptor to depart from the using utility power.



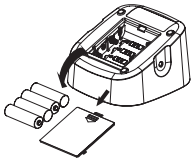
⚠ CAUTION

In order to get the best effect and protect your monitor,please use the right battery and special power adaptor which complies with U.S. 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.

The typical service life of the new and unused batteries is 300 measurements for the operation time is 60s.



Replace the batteries whenever the below happen

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

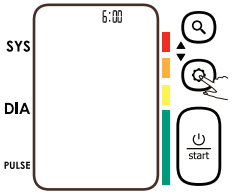
⚠ CAUTION

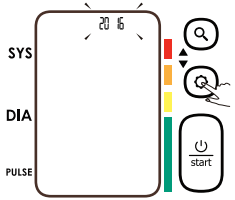
- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Do not dispose the batteries in fire. Batteries may explode or leak.
- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose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

♥ Setting Date, Time and Measurement Unit

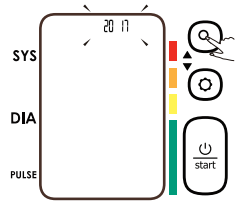
It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of the year :2016—2056; Time format:24H)

1. When the monitor is off, press " ☼ "button,it will display the time.Then press and hold " ☼ " button to enter the mode for year setting.
(Notes:
1.During the process of setting, you can press " start " button to stop setting at any time.
2. If there is no operation during the process of setting, it will turn off within 1 minute.)

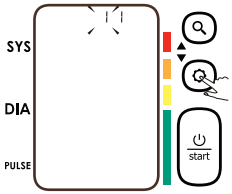




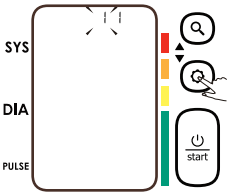
2. Press " 🔍 " button to change the [YEAR]. Each press will increase the numeral by one in a cycling manner.

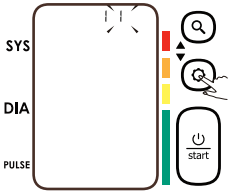


3. When you get the right year, press “ ☼ ” button to set down and turn to next step.

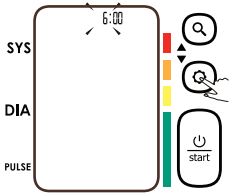


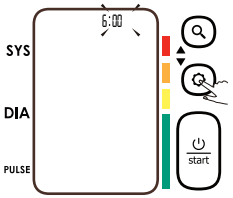
4.Repeat steps 2 and 3 to set the [MONTH] and [DAY].



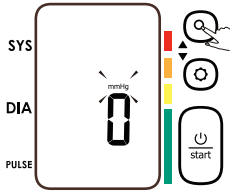


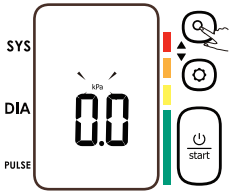
5.Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].



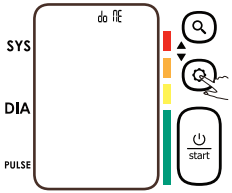


6.Repeat steps 2 and 3 to set the [UNIT].



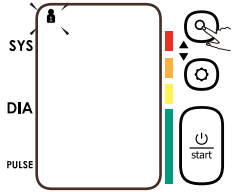


7. After the unit is set,the LCD will display “done” first, then display all the settings you have done and then turn off.

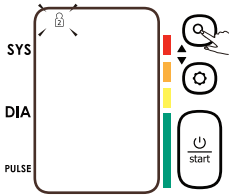


♥ Select the User

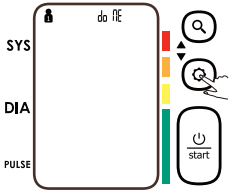
1. When the monitor is off, press and hold " 🔍 "button to enter user setting mode. The user ID will blink.



2. Then press " 🔍 " button again, select the user ID between user 1 and user 2.



3. After selecting the suitable user ID, press " ☼ " button to confirm. It will display User ID+ donE" and then turn off.

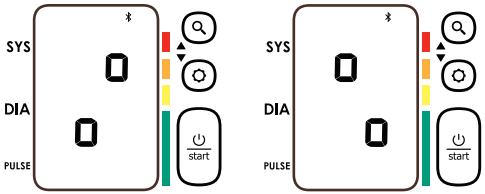


♥ Pair - up the Blood Pressure Monitor with Your Device

Before you start pairing, please download the MedM Health app from APP Store or Google Play in your device which supports Bluetooth 4.0 technology first.

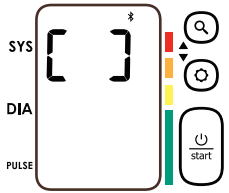
1. Turn on Bluetooth and the app. Make sure both are ON when pair-up is proceeding. If this is the first time you use "MedM Health", please register an account first. Enter your account and password to log in.Please enter "My Profile" to set your pernal information. Please enter Settings infterface,click "My Devices", select "Add the Device".

2. When the monitor is OFF, press and hold the start button to start pair-up. The symbol and will display alternatively, indicating pair-up is proceeding.

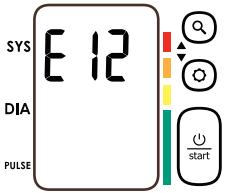


3. After detecting the blood pressure monitor, "MedM Health" will display the product's information. Click and select the device which you want to bind with your mobile device. Click "bind the device", then click "User Profile" to select the user you want to connect with your mobile device on the app to continute the pair-up. After binding the device, it only can transmit the data of the bound user.

If SUCCEED, symbol + [ ] will be shown on the LCD.



If FAIL, only bluetooth symbol "E12" will be shown on the LCD.



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

Bluetooth Module No.: AW51822
RF Frequency Range: 2402 MHz to 2480 MHz
Output Power Range: 4 dBm
Supply Voltage: 1.8V-3.6 V
Transmitting Distance: 10 meters

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

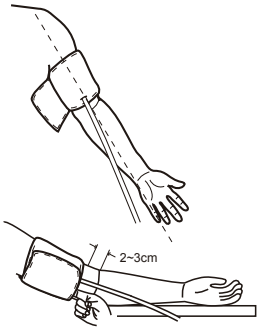
⚠CAUTION

- Interference may occur in the vicinity of equipment marked with the following symbol . And TMB-1597-BN may interfering vicinity electrical equipment.
- Sensitive people, including pregnant women pre-eclamptic and those who implanted medical electronic instruments, should avoid using the unit whenever possible.
- Keep the monitor at least 20 centimeters away from the human body (especially the head) when the data transmission is proceeding after measurement.
- To enable the data transmission function, this product should be paired to Bluetooth end at 2.4 GHz.

How to mitigate possible interference?

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

♥ Tie the cuff



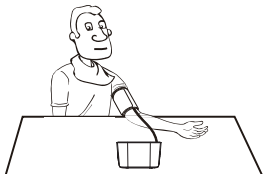
1. Tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger. Or position the artery mark ϕ over the main artery (on the inside of your arm). Note: Locate the main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.

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

3. Sit comfortably with your tested arm resting on a flat surface.

4. Patients with Hypertension:
The middle of the cuff should be at the level of the right atrium of the heart; Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported.

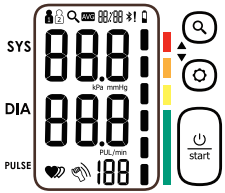
- Rest for 5 minutes before measuring.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, position of upper arm, or as directed by a physician.



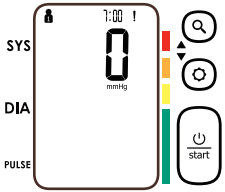
♥ Start the Measurement

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

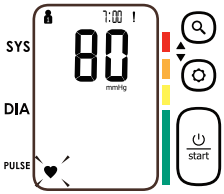
LCD display



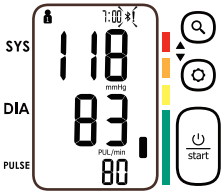
Adjust the zero.



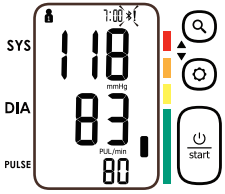
Inflating and measuring.



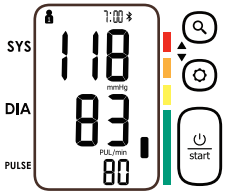
Display and save the measurement results. The year, date and time will display alternately.



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



Transmitting



Complete

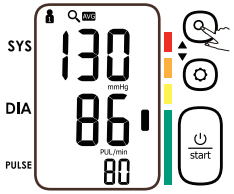
3.With TMB-1597-BN successfully pair-up with your mobile device, the measurement data will be automatically transmitted to your mobile device via Bluetooth.
(1).The symbol ! will disappear after successful data transmission, and you may check your personal health data stored in your mobile device.
(2).If the data transmission fails, the symbol ! will remain. The pending measurement data will be transmitted to your mobile device when next measurement is complete.

4. Press the " start " button to power off, otherwise it will turn off within 1 minute.

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

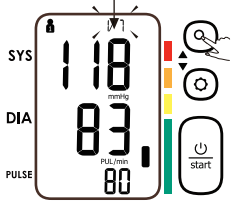
♥ Recall the Records

1. When the monitor is off, please press " 🔍 " button to show the average value of the latest three records.
(Take user 1 for example.)

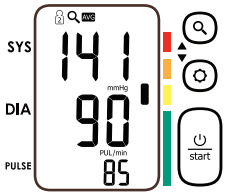


2. Press " 🔍 " button or " ☼ " button to get the records you want.

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



3. If you want to check another user's records, press " ⏻ start " button to turn off the monitor when the blood pressure monitor is in the memory inquiry mode. Press and hold " 🔍 " button to enter into the selecting user ID mode, press " 🔍 " button again to select the user ID between user 1 and user 2, press " ☼ " button to confirm the user ID , then press " 🔍 " button to check the selected user's measurement records.



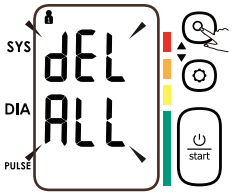
⚠ CAUTION

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

♥ Delete the Records

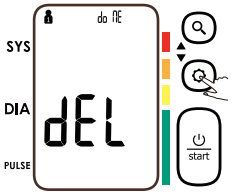
If you did not get the correct measurement, you can delete all results for the selected user by following steps. (Take User 1 for example.)

1. Hold pressing " 🔍 " button about 3 seconds when the monitor is in the memory recall mode, the flash display " dEL ALL"+ User ID will show.

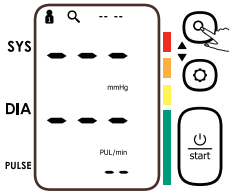


Note: To exit out of delete mode without deleting any records, press " start " button before pressing " ☼ " button to confirm any delete commands.

2. Press " ☼ " button to confirm deleting and the monitor will display "User ID+dEL dOnE" and then turn off.

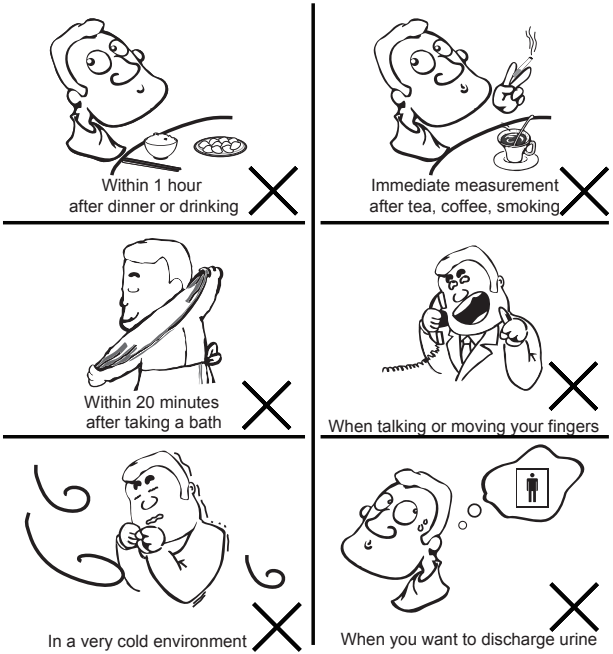


3. If there is no record, when you press " 🔍 " button to check the record, the following display will show.



♥ Tips for Measurement

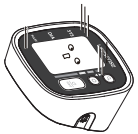
Measurements may be inaccurate if taken in the following circumstances.



♥ 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

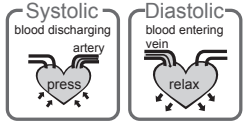
Avoid touching water, clean it with a dry cloth in case.

Avoid dusty and unstable temperature environment

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

♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



♥ What is the standard blood pressure classification?

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

AHA Home Guideline for Upper Limit of Normal BP

SYS	135 mm Hg
DIA	85 mm Hg

This chart reflects blood pressure categories defined by American Heart Association.

Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Normal	less than 120	and	less than 80
Prehypertension	120-139	or	80-89
High Blood Pressure (Hypertension) Stage 1	140-159	or	90-99
High Blood Pressure (Hypertension) Stage 2	160 or higher	or	100 or higher
Hypertensive Crisis (Emergency care needed)	Higher than 180	or	Higher than 110

⚠ 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.

♥ Irregular Heartbeat Detector

An irregular heartbeat (IHB) is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure.During each measurement, the monitor records the heartbeat intervals and calculates the average. If any average is larger than or equal to 25%,the irregular heartbeat symbol appears on the display when the measurement results appear.

⚠ 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 a different blood pressure at home compared to the hospital?

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

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

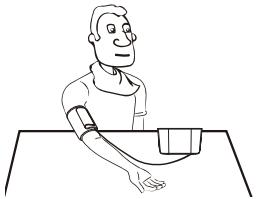
If the cuff is tied properly.
If the cuff is too tight or too loose.
If the cuff is tied on the upper arm.
If you feel anxious.

Taking 2-3 deep breaths before beginning will be better for measuring.

Advice: Relax yourself for 4-5 minutes until you calm down.

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

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



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

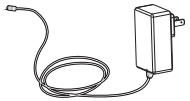
PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Display is dim or show	Batteries are low.	Replace with new batteries
Error message	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.
	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.
	E 12 shows	Data communication is failed.	Check if the App/Bluetooth is on or not,try data transmission 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 then measure again. If the problem persists, contact your physician.

Power supply	Battery powered mode: 6VDC 4×AA alkaline batteries AC adaptor powered mode: 6V ⎓ 1A (Please only use the recommended AC adaptor model).
Display mode	Blue LCD display with white backlight V.A.73mm×49mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~300mmHg(0kPa ~ 40kPa) 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℃-40℃within±3mmHg(0.4kPa) Pulse value:±5%
Normal working condition	A temperature range of :+5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of : 700 hPa to 1060 hPa
Storage & transportation condition	Temperature:-20°C to +60°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the upper arm	About 22cm~32cm or 22cm~42cm
Weight	Approx.258g(Excluding the dry cells and cuff)
External dimensions	Approx.118mm×126mm×72mm
Attachment	4×AA alkaline batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 It means the device could protected against solid foreign objects of 12.5mm and greater, and protect against vertically falling water drops.
Software Version	A01

WARNING: No modification of this equipment is allowed.

♥ Authorized Component

1. please use the TRANSTEK authorized adapter.



Adapter
Model：KH0601000UW
Input：AC 100-240V
50/60Hz 0.4A Max
Output：6V ⎓ 1000mA

♥ Contact Information

For more information about our products, please visit www.transtek.cn.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

♥ Complied Standards List

Risk management	ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labeling	ISO 15223-1:2012 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	IEC 60601-1: 2005+A1： 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-11 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	IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
Performance requirements	IEC 80601-2-30:2009 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	ISO 81060-2:2009 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	IEC 62366 Medical devices - Application of usability engineering to medical devices (IEC 62366:2007) IEC 60601-1-6 Medical electrical equipment - Part 1 -6 : General requirements for basic safety and essential performance - collateral standard : Usability
Software life-cycle processes	IEC 62304:2006/AC: 2008 Medical device software - Software life-cycle processes

♥ FCC Statement

FCC ID: OU9TMB1597BN

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.

MODIFICATION: Any changes or modifications not expressly approved by the grantee of this device could void the user’s authority to operate the device.

♥ EMC Guidance

1)This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2)* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3)Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4)* Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Table 1 Guidance and MANUFACTURER's declaration – ELECTROMAGNETIC EMISSIONS- for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
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, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 Guidance and MANUFACTURER's declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode	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	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	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 4 Guidance and MANUFACTURER's declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

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
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a 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 6 Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

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 (transmittters) 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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 ***d*** in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80MHz and 800MHz, 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.			