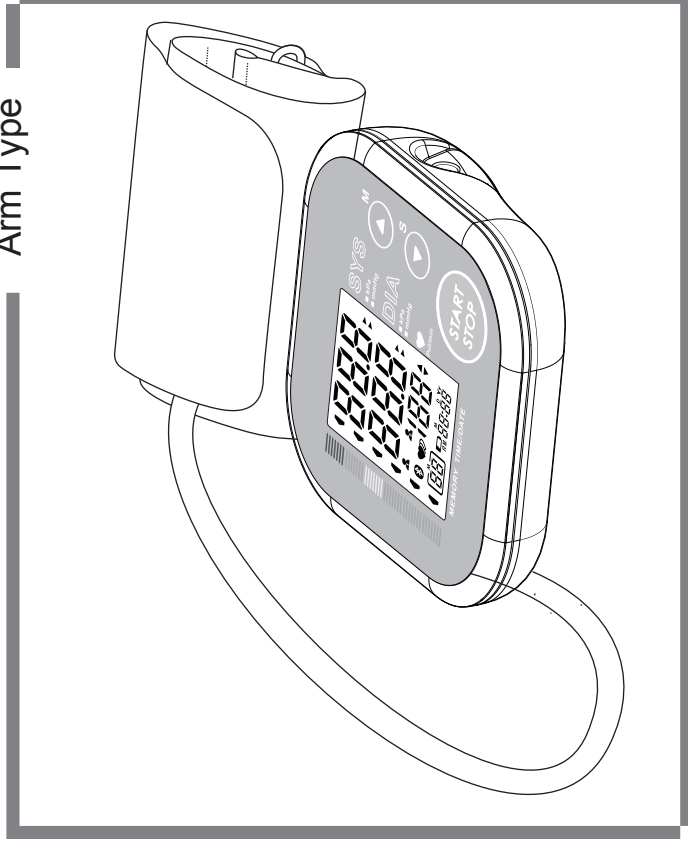


User Manual

Blood Pressure Monitor TMB-1491-BT

Arm Type



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

- Thank you very much for selecting TRANSTEK Blood Pressure Monitor TMB-1491-BT.
- Please do read the user manual carefully and thoroughly so as to ensure the safe usage of this product, and keep the manual well for further reference in case you have problems.

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♥ General Description

Thank you for selecting **TRANSTEK** arm type blood pressure monitor (TMB-1491-BT). 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-1491-BT 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:

- 60mm×40.5 mm Digital LCD display
- Maximum 60 records
- 3rd technonoly: Measuring during inflation (The updated technology in the world)

♥ 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.

♥ 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"
	The Bluetooth Combination Mark		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 "MANUFACTURER"		Symbol for "Including RF transmitter"
	Symbol for "SERIAL NUMBER"		For indoor use only
	Symbol for "DIRECT CURRENT DATE"		Symbol for "Class II Equipment"
F1	T1A/250V ø3.6*10CCC		

CAUTION

This device is intended for adult use only.

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 with oxygen or nitrous oxide.

The operator shall not touch output of batteries/AC adaptor 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 sensitization or irritation reaction.

The device has been evaluated clinically using manual cuff/stethoscope auscultation as the reference. Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, Manual, electronic, or automated sphygmomanometers."

The patient is an intended operator. The patient can measure under normal circumstances and maintain the device and its accessories according to the user manual.

The blood pressure monitor, and the cuff are suitable for use within the patient environment. If you are allergic to dacron or plastic, please don't use this device.

Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.

If 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.

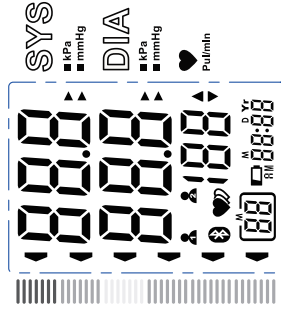
The device is not suitable for public use.

The device is not intended for PATIENT transport outside a healthcare facility.

This device cannot be used with HF surgical equipment at the same time.

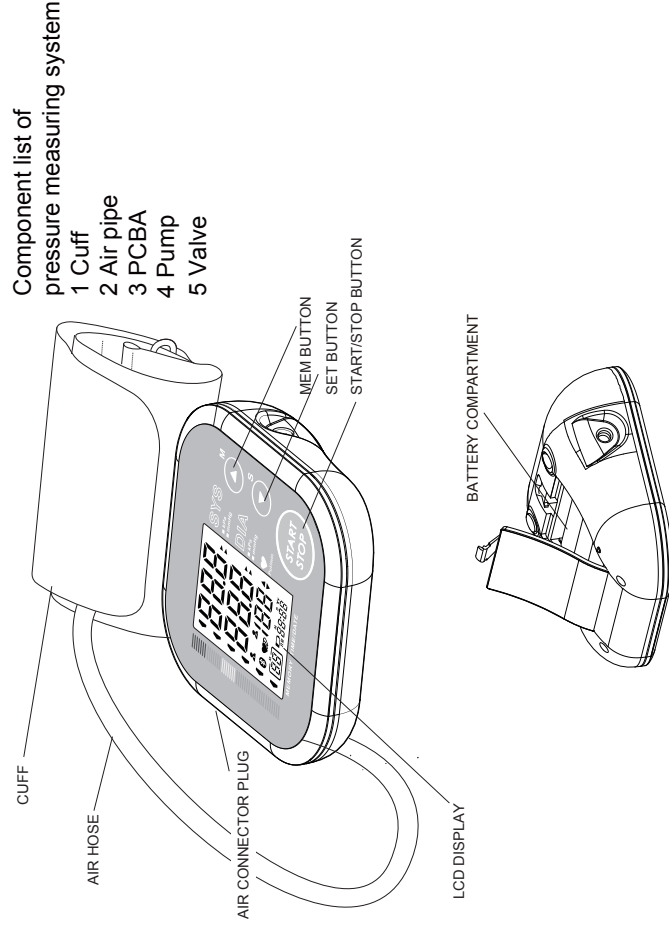
Be careful to strangulation due to cables and hoses, particularly due to excessive length.

♥ LCD display signal



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
Pul/min	Pulse per minute	Beats per minute, BPM
▼	Deflating	CUFF air is exhausting of deflating
	Memory	The displayed measurement values is from the memory.
kPa	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
	Low battery	Batteries are low and need to be replaced
	Arrhythmia	Irregular heartbeat
	Grade	The grade of the blood pressure
	Current Time	Year/Month/Day, Hour/Minute
	Heartbeat	Heartbeat detection during the measurement
	User 1	Start measurement,save and transmit the measuring results for User 1
	User 2	Start measurement,save and transmit the measuring results for User 2
	Bluetooth icon	The bluetooth icon blinks when the bluetooth is working

♥ Monitor Components



♥ List

1. Blood Pressure Monitor (TMB-1491-BT)

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

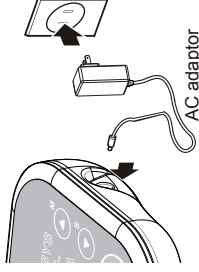
 3. 4×AAA alkaline batteries

 4. User manual
 5. AC Adaptor (Model : KH0601000UW)

♥ The Choice of Power Supply

1. Battery powered mode:
6VDC 4×AAA alkaline batteries
2. AC adaptor powered mode:
6V $\approx$ 1A
(Please only use the recommended AC
adaptor model).

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

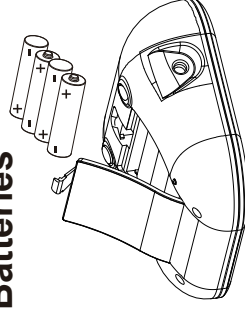


CAUTION

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 cover.



Replace the batteries whenever the below happen

- The  shows
- The display dims
- The display does not light up



CAUTION

- Remove batteries if the device is not likely to be used for some time.
- The old batteries are harmful to the environment, do not dispose with other daily trash.
- Remove the old batteries from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.

♥ 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%.



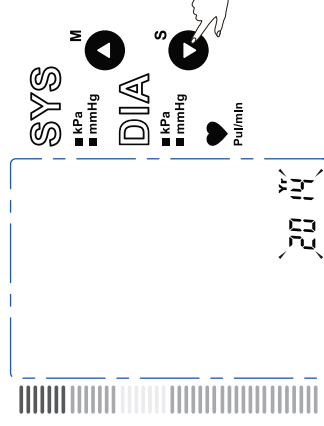
CAUTION

- 1: 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: 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 upper arm on the side of a mastectomy.
2. Do not apply the cuff over a wound, otherwise it can cause further injury.
3. 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.
4. Using it in case to result in prolonged impairment of the circulation of the blood of the PATIENT.
- 5: Don't kink the connection tube, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.

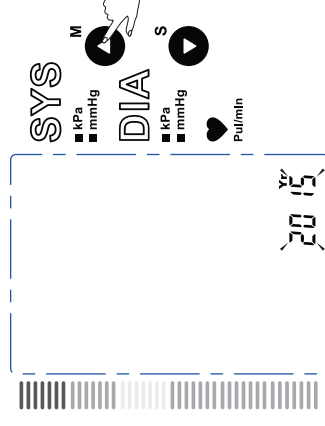
♥ Setting Date, Time and Measurement Unit

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 :2014—2054 time format:12H / 24H)

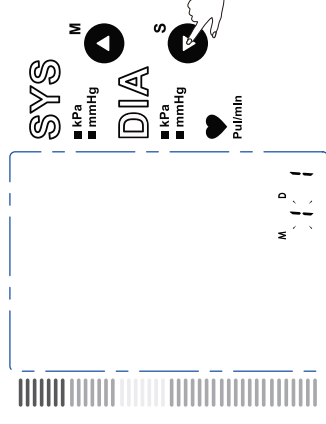
1. When the monitor is off, hold pressing "SET" button for 3 seconds to enter the mode for year setting. Or when the monitor is off, press "SET" button shortly, it will display the time. Then hold pressing "SET" button to enter the mode for year setting.



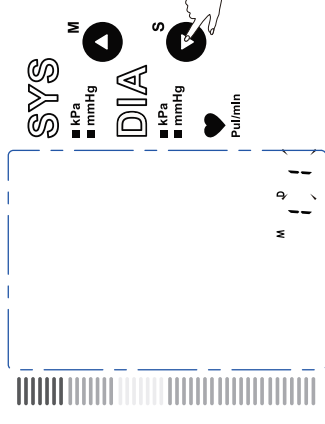
2. Press the "MEM" button to change the [YEAR].



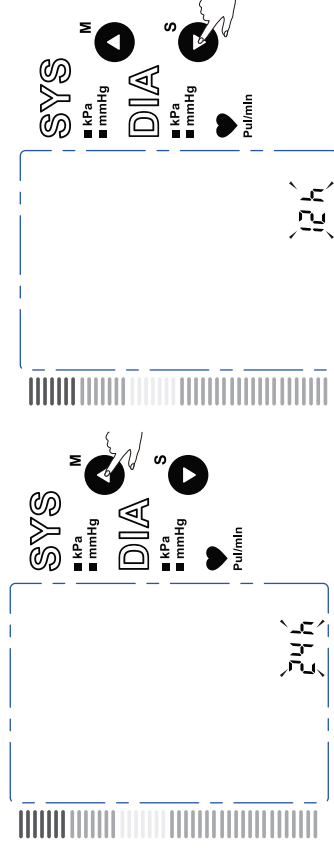
3. When you get the right year, press "SET" button to set down and turn to next step.



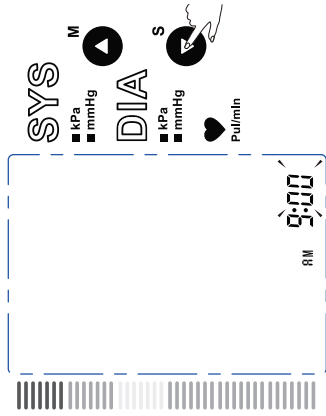
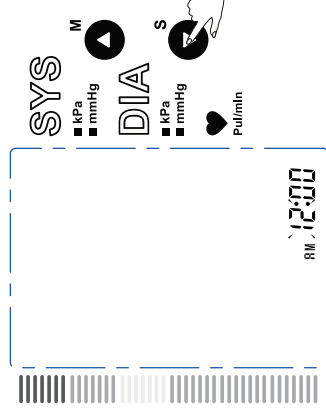
4. Repeat steps 2 and 3 to set the [MONTH] and [DAY].



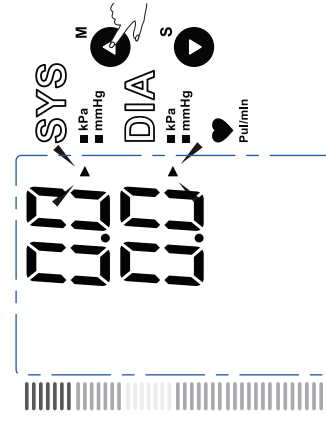
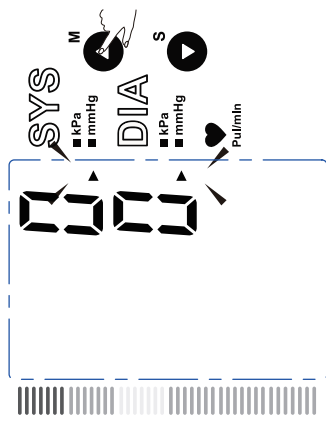
5. Repeat steps 2 and 3 to set the [TIME FORMAT].



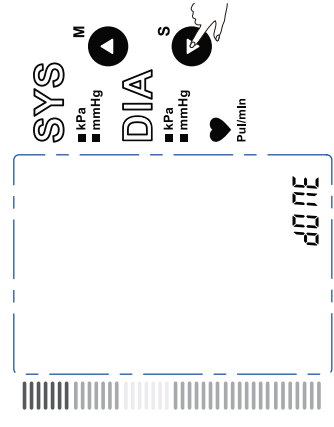
6. Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].



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

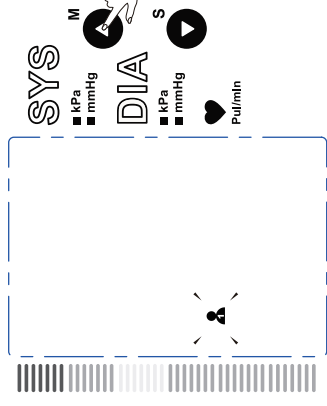


8. After the unit is set, the LCD will display "done" and then turn off.

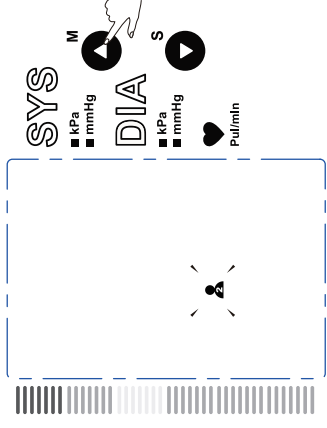


♥ Select the User

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



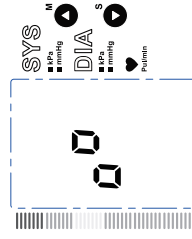
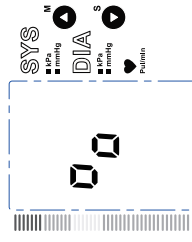
2. Then press MEM button again, select the user ID between user 1 and user 2.



3. After selecting the suitable user ID, press SET button to confirm. Then the LCD will turn off.

♥ Pair-up the Blood Pressure Monitor with Your Device

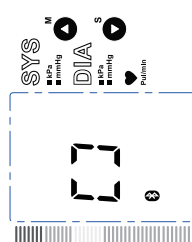
1. Turn on Bluetooth and the app. Make sure both are ON when pair-up is proceeding.
2. When the monitor is OFF, press and hold the START/STOP button to start pair-up. The symbol  and  will be shown on the LCD alternatively, indicating pair-up is proceeding.



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

If SUCCEED, symbol  will be shown on the LCD.

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

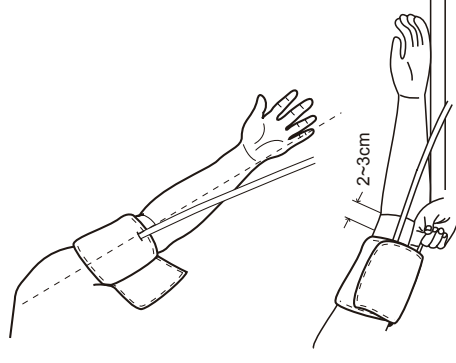


4. The monitor will shut off after Pair-up process is complete.

Bluetooth Module No.: AW8001
RF Frequency Range: 2402 MHz to 2480 MHz
Output Power Range: 0 dBm
Supply Voltage: 1.8-3.6 V
Transmitting Distance: 10 meters

♥ Tie the cuff

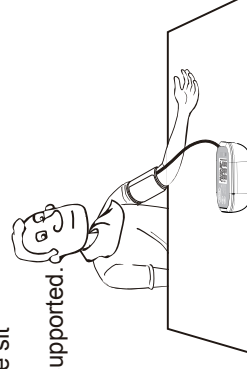
1. Tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger.
2. The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.



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.

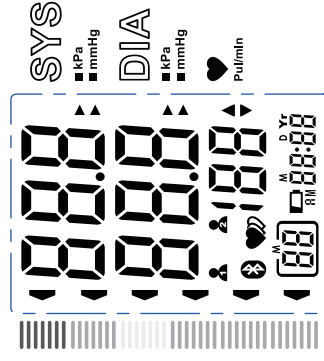


- Rest for 5 minutes before measuring.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, position of upper arm, or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

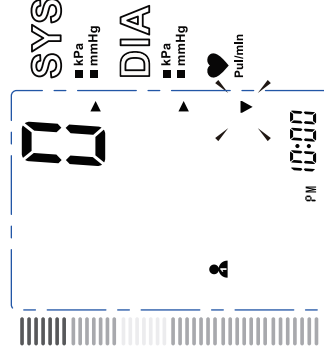
♥ Start the Measurement

1. When the monitor is off, press the "START/STOP" button on the monitor, and it will finish the whole measurement.

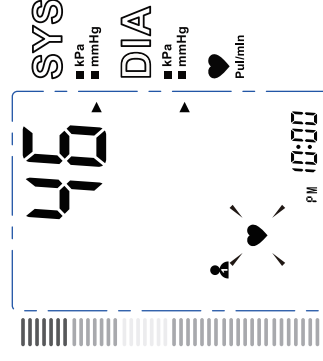
LCD display



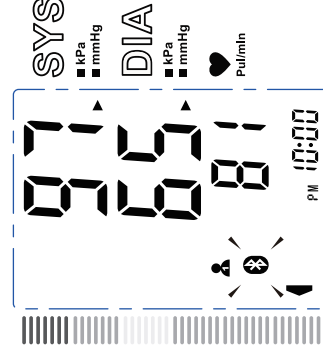
Adjust to zero.



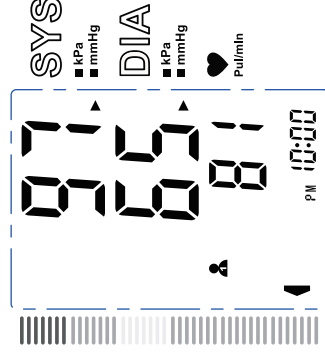
Inflating and measuring.



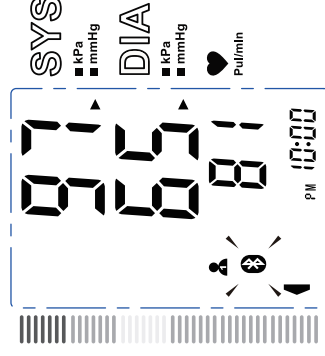
Display and save the results.
The device will proceed to data transmission after measurement.
The Bluetooth symbol blinks on the LCD indicates data is transmitting.



If the data transmission succeeds, the Bluetooth symbol will disappear.



If the data transmission fails, the Bluetooth symbol blinks all the time until it turns off.

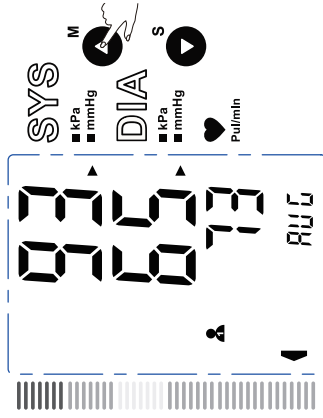


2. Press the "START/STOP" button to power off, otherwise it will turn off within 1 minute.

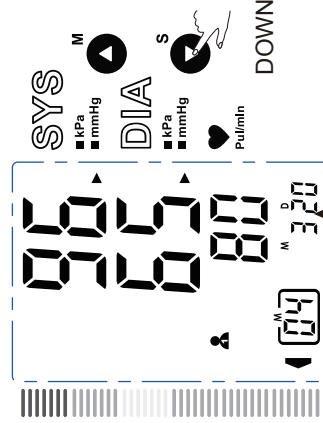
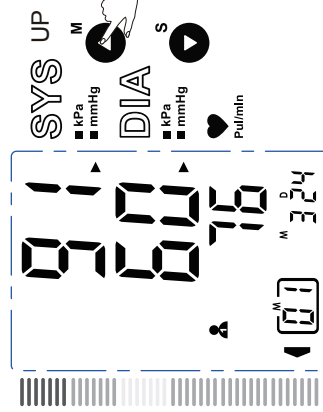


♥ Recall the Records

1. When the monitor is off, please press “MEM” button to show the average value of the latest three records.



2. Press “MEM” button or “SET” button to get the record you want.



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

[04]

M 320

PM 10:00

The current No. is No. 4. The corresponding date is March 20th.

The corresponding time is P.M. 10:00.



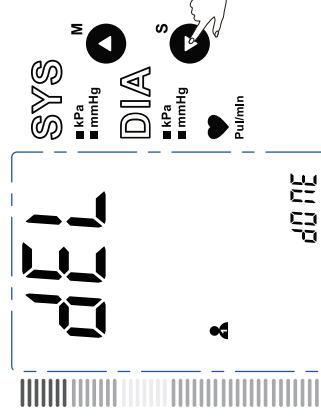
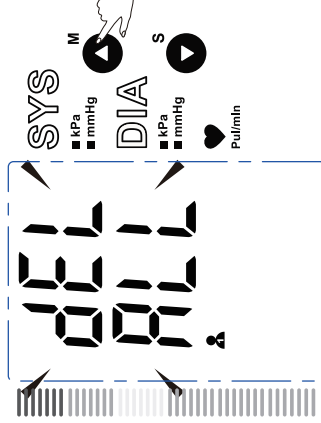
CAUTION

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 by following steps below.

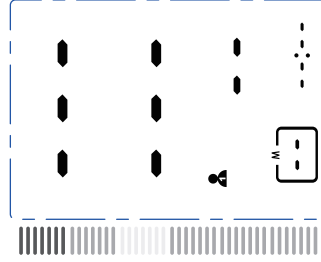
1. Hold pressing “MEM” button for 3 seconds when the monitor is in the memory recall mode, the flash display will show.



3. If you don't want to delete the records, press “START/STOP” button to escape.

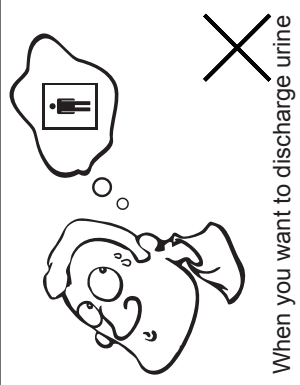
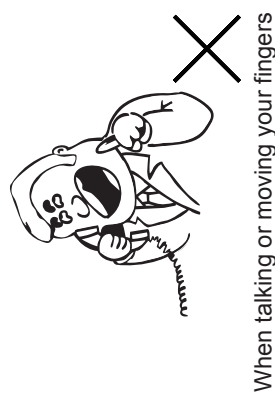
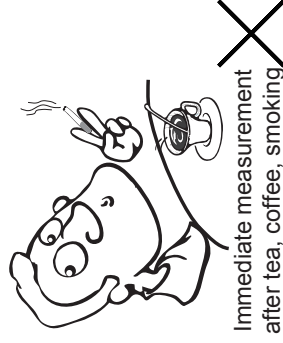
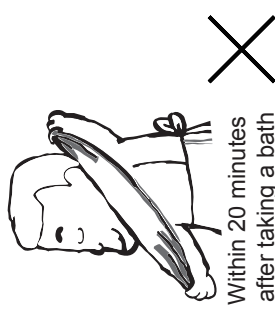
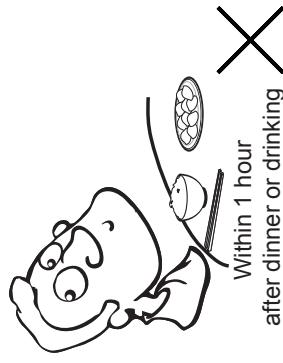


4. If there is no record, the right display will show.



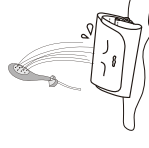
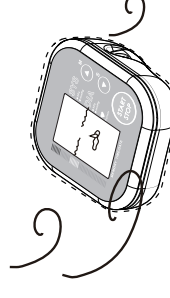
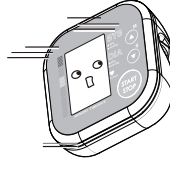
♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.



♥ Maintenance

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

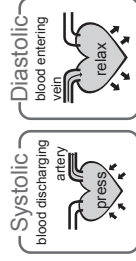


CAUTION

Please use ACCESSORIES and detachable parts 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 the two years of reliable service. Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines. 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.

♥ 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
D/A	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



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

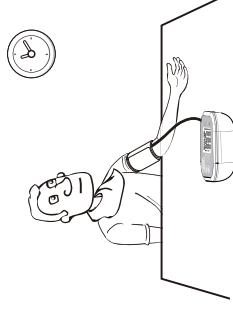
An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, the irregular heartbeat symbol appears on the symbol when the measurement results are displayed.



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?

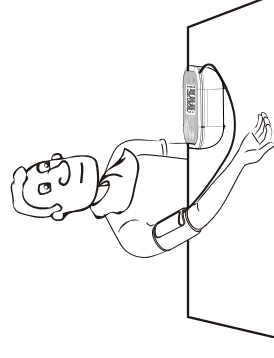
The blood pressure is different even throughout the day due to weather, emotion, exercise etc. Also, there is the "white coat" effect, which means blood pressure usually increases in clinical settings.

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.

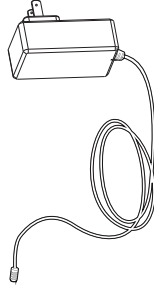
PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Display is dim or shows 	Batteries are low.	Replace with new batteries
	E 1 shows	Data communication is failed.	Check if the App/Bluetooth is on or not, try data transmission again.
	E 3 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E10 or E11 shows	The monitor detected motion, talking or the pulse is too poor while measuring.	Relax for a moment and then measure again.
	E20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again
	E21 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	EExx shows on the display.	A calibration error occurred.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions.

Power supply	Battery powered mode: 6VDC 4×AAA alkaline batteries AC adaptor powered mode: 6V $\pm$ 1A (Please only use the recommended AC adaptor model).
Display mode	Digital LCD V.A.60mm×40.5mm
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±0.4kPa(3mmHg) pulse value: ±5%
Normal working condition	Temperature: 5℃ to 40℃ Relative humidity: ≤85%RH Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature: -20℃-60℃ Relative Humidity: 10%RH-93%RH Atmospheric Pressure: 50kPa-106 kPa
Measurement perimeter of the upper arm	About 22cm~32cm or 22cm~42cm
Net Weight	Approx. 180g(Excluding the dry cells)
External dimensions	Approx. 110mm×110mm×41mm
Attachment	4×AAA alkaline batteries, user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21
Software Version	V01

WARNING: No modification of this equipment is allowed.

♥ Authorized Component

1. please use the TRANSTEK authorized adapter.



Adapter
Type: KH0601000UW
Input: 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 A, No.105 ,Dongji Road, Torch Development District, Zhongshan,528437, Guangdong, China

♥ Complied Standards List

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
User manual	EN 1041: 2008 Medical equipment manufacturers to provide information
General Requirements for Safety	IEC 60601-1: 2005+A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Electromagnetic compatibility	IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard Electromagnetic compatibility - Requirements and tests
Performance requirements and Clinical Investigation	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 ANSI/AAMI SPO-2002/A2: 2008 Manual, electronic, or automated sphygmomanometers
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

♥ FCC Statement

FCC ID: OU9TMB1491-B

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.

♥ EMC Guidance

1. MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS

2. 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=3, 3m away from the equipment.

(Note: As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d=3, 3m at an IMMUNITY LEVEL of 3V/m)