CE 0123

GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD
Zone A, 5/F., Investment Building, No. 12, Huizhan East Rd., Torch Development District, Zhongshan, Guangdong, 528437, China

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

TRANSTEK

CE 0123

version:1.0

TRANSTEK

User Manual

Blood Pressure Monitor TMB-1490

Arm Type

- Thank you very much for selecting TRANSTEK Blood Pressure Monitor TMB-1490.
- 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.

Table of Contents

♥ General Description

Thank you for selecting TRANSTEK arm type blood pressure Monitor (TMB-1490). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.

Reading taken by the TMB-1490 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 instruction for using the product.

Read the manual thoroughly before using the product.

Features:

- 60×92 mm Bright LCD display
- Maximum 250 records
- 3rd technonoly: Measuring during inflation (The updated technology in the world)

♥ Safety Information

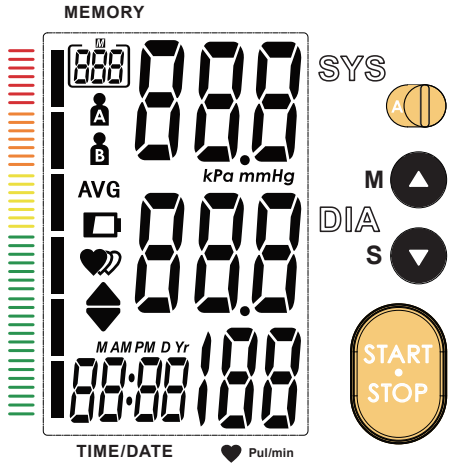
The below signs might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
CE 0123	Symbol for “COMPLIES WITH MDD 93/42/EEC REQUIREMENTS”		Symbol for “ENVIRONMENT PROTECTION - Wast electrical 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”		
SN	Symbol for “SERIAL NUMBER”		
⎓	Symbol for “DIRECT CURRENT”	EC REP	Symbol for “Authorised Representative in the European Community
	Symbol for “MANUFACTURE DATE”		For indoor use only
F1	T1A/250V Φ3.6*10CCC		Symbol for “Class II Equipment”

CAUTION

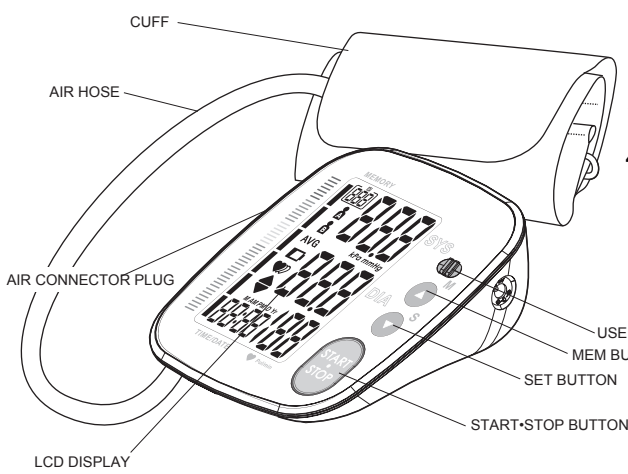
This device is intended for adult use only.
This device is intended for no-invasive measuring and monitoring of arterial blood pressure.
It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement.
Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure.Do not begin or end medical treatment based solely 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 artrial fibrillation, the best result may occure 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 armand 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 provided inaccurate readings, the affects 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 been impacted and reduced.
During using, the patient will 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 in 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 with 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.
The adaptor is specified as a part of ME equipment.
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 adapter insulates the device from the main supply. Do not position the plug in a position where it is difficult to disconnect from the supply mains.
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.
The patient is an intended operator. The patient can measure,query records and change battery under normal circumstances and maintain the device and its accessories according to the user manual.
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.
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.
Using it in case to result in prolonged impairment of the circulation of the blood of the PATIENT.
Don't link the connection tube, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.

♥ LCD display signal

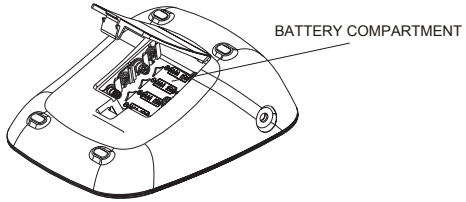


SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
Pul/min	Pulse per minute	Beats per minute, BPM
▼	Deflating	CUFF air is exhausting of deflating
M	Memory	The displayed measurement values is from the memory.
kPa	kPa	Measurement Unit of the blood pressure
mmHg	mmHg	Measurement Unit of the blood pressure
Lo+	Low battery	Batteries are low and need to be replaced
	Arrhythmia	Irregular heartbeat
	Grade	The grade of the blood pressure
M AM PM D Yr	Current Time	Year/Month/Day, Hour/Minute
A	User A	Start measurement for User A
B	User B	Start measurement for User B
♥	Heartbeat	Heartbeat detection during the measurement
AVG	The average value	The average value of the latest three records

♥ Monitor Components



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

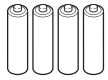


♥ List

1.Blood Pressure Monitor (TMB-1490)

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

3. 4×AAA batteries



4.User manual

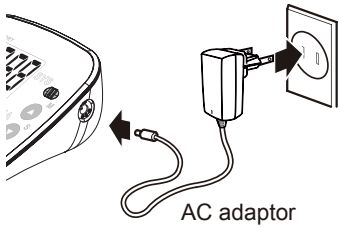
5. AC Adaptor (UE08WCP-060100SPA)

♥ The Choice of Power Supply

1.Battery powered mode:
6VDC 4×AAA 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.

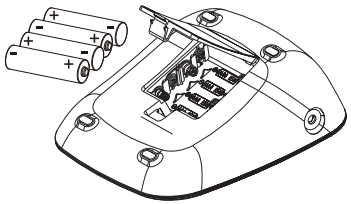


CAUTION

In order to get the best effect and protect your monitor,please use the the right batteries and special power adapter. which complies with CE 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 Lo+ 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, so please disposal 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

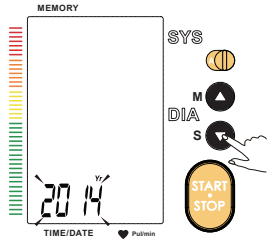
This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the air pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, 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 displays a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.

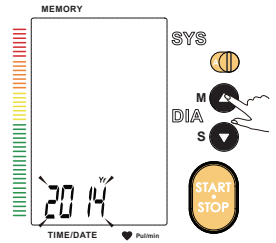
♥ Setting Date, Time and Measurement Unit

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:12 H/24H)

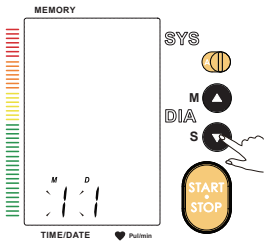
1.When the monitor is off, hold pressing “SET” for 3 seconds to enter the mode for year setting.
Or when the monitor is off, press “SET” button shortly, it will display the time. Then hold pressing “SET” button to enter the mode for year setting.



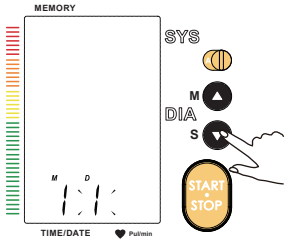
2.Press the “MEM” to change the [YEAR].



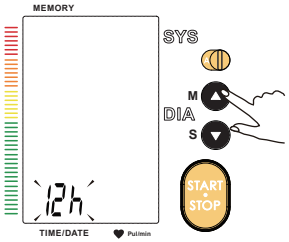
3.When you get the right year, press “SET” to set down and turn to next step.

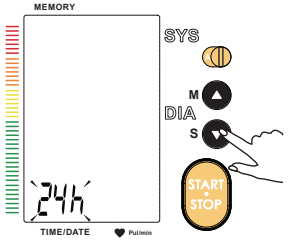


4.Repeat step 2 and 3 to set the [MONTH] and [DAY].

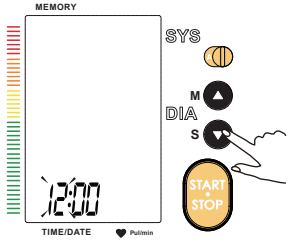


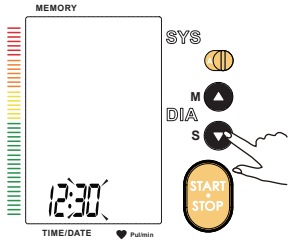
5.Repeat step 2 and 3 to set the [TIME FORMAT] between 12h and 24h.



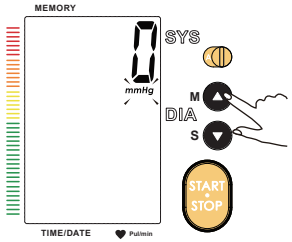


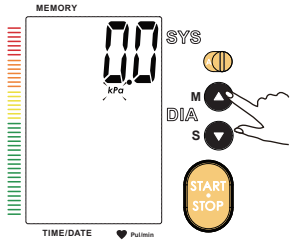
6.Repeat step 2 and 3 to set the [HOUR] and [MINUTE].



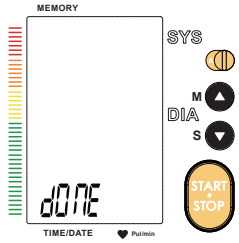


7.Repeat step 2 and 3 to set the [UNIT].



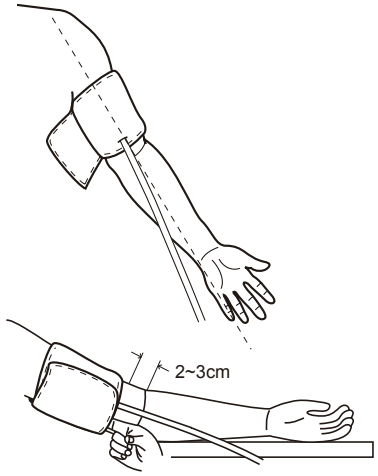


8.After the unit is set,the LCD will display “dOnE”first,then display all the settings you have done and then it will turn off.



♥ Tie the cuff

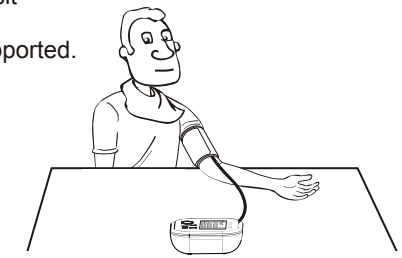
1.Tie the cuff on your upper arm, the position the tube off-center toward the inner side of arm in line with the little finger.



2.The cuff should be sung 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.

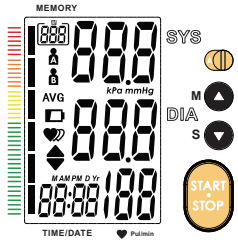


• Resting For 5 minutes before measuring.
• Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
• For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, position of upper arm,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

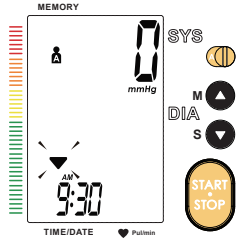
♥ Start the Measurement

1.Before you start the measurement, 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 finish the whole measurement. And save the measurement data for the desired user. (Take User A for example.)

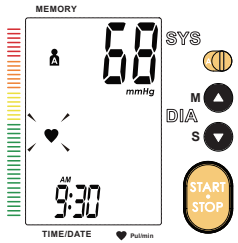
LCD display



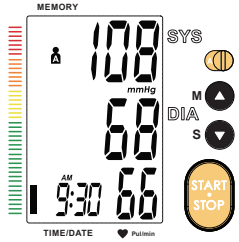
Adjust the zero.



Inflating and measuring.



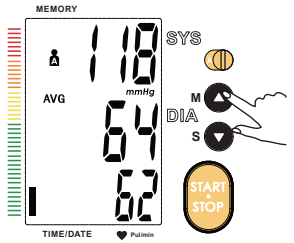
Display and save the measurement result.



2.Press the “START•STOP” to power off, otherwise it will turn off within 1 minute.

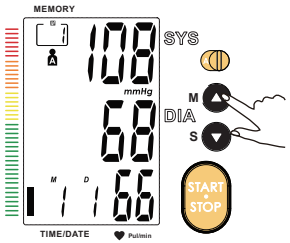
Tips: Maximum 250 records are both for User A and User B.

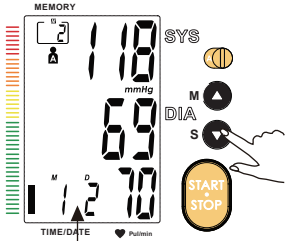
♥ Recall the Records



1. When the monitor is off, please press the “MEM”,it will display the latest record first when the records are less than three groups. When there are more than three groups ,it will display the average value of the latest three records first.

2. Press the “MEM” or “SET” to get the record you want. Press and hold the “MEM” button to look over ten groups of the historical records quickly.





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

The current No. is No 2.

The corresponding date is January 2nd.

The corresponding time is P.M. 10:08.

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

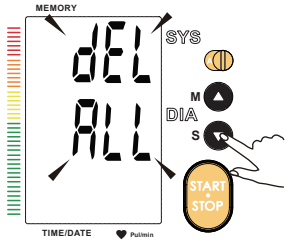
CAUTION

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.

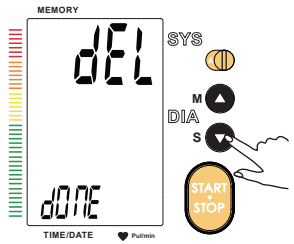
♥ Delete the Records

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

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

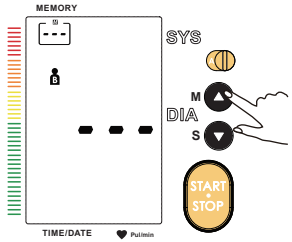


2.Press “SET” to confirm deleting and the monitor will turn off.



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

4. If there is no record. Press “MEM” button, the right display will show.



♥ Tips for Measurement

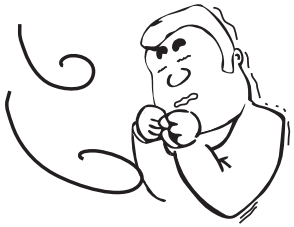
It can cause inaccuracy if the measurement is taken in the following circumstances.

Within 1 hour
after dinner or drinking

Immediate measurement
after tea, coffee, smoking

Within 20 minutes
after taking a bath

When talking or moving your fingers



In a very cold environment

When you want to discharge urine

♥ Maintenance

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

Put in a dry place and
avoid the sunshine

Avoid the intense shaking
and collision

Using the wet clothing to
remove the dirt

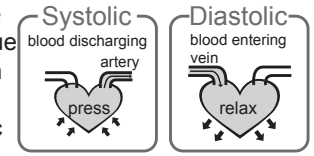
Avoid touching water,
clean it with a dry cloth in case.

Avoid the dusty and unstable-
temperature environment

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

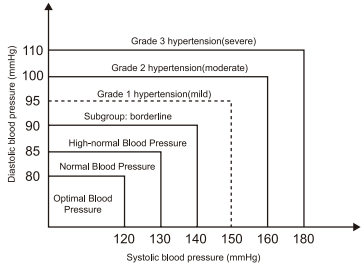
♥ What are systolic pressure and diastolic pressure?

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 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.
Kindly note that only a physician could tell whether your blood pressure value has reached a dangerous point.

Blood Pressure (mm Hg) \ 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

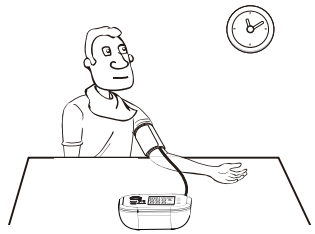
This Blood Pressure Monitor is equipped with an intelligent function of Irregular Heartbeat (IHB) Detector. During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, this equipment will light up the IHB symbol on the screen when displaying the measuring result.

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 every in one day, it also affected by the way you tie your cuff and the your measurement position, so please take the measurement at the same condition.
2. The variations in the pressure can be greater or smaller, depending on the actual medicine taken.
3. Waiting at least 3 minutes for another measurement.



♥ Why the blood pressure I get from the hospital is different from home?

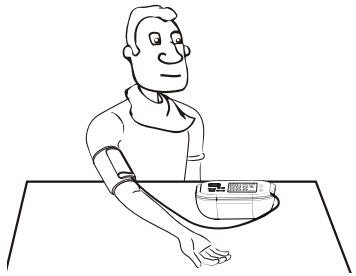
The blood pressure is different even during 24 hour because of the weather,emotion, exercise etc, specially the “white coat” in hospital which makes the results are higher than the ones at home.

The attention need to pay when you measure you 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 pressured.
You had better take deep breath 2-3 times before beginning.
Advice:adjust yourself for 4-5 minutes until you calm down.

♥ If the result is the same if measuring on the right arm?

It is ok for both arms, but there will be some different results for different person, so 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.

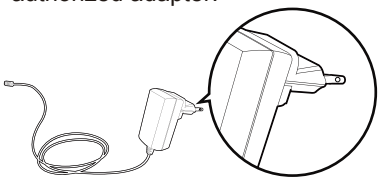
PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Display is dim or show	Batteries are low.	Replace with new batteries
Error massage	E 1 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E 2 shows	The cuff is very tight	Readjust the cuff ,not too loose or too tight and then measure again.
	E 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	E10 or E11 shows	The monitor detected motion,talking or the pluse 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 (XX can be some numeric characters,such as 01, 02 and so on .	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 batteries AC adaptor powered mode: 6V ⎓ 1A (Please only use the recommended AC adaptor model).
Display mode	Digital LCD V.A.60×92mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0kpa - 40kpa (0mmHg~300mmHg) Measurement pressure: 5.3kPa-30.7kPa (40mmHg-230mmHg) 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% Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20℃-60℃ Relative Humidity 10%-93% Atmospheric Pressure: 50-106 kPa
Measurement perimeter of the upper arm	About 22~32cm or 22cm~42cm
Net Weight	Approx.250g(Excluding the dry cells)
External dimensions	Approx.140×130×49.7mm
Attachment	4×AAA 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：UE08WCP-060100SPA
Input：100~240V，50~60Hz,400mA
Output：6V ⎓ 1A
(Conforms to UL certificate)

♥ 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, 5/F., Investment Building , No. 12, Huizhan East Rd., Torch Development District, Zhongshan, Guangdong, 528437, China

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

♥ Complied European Standards List

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	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	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11: 2010 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 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard:Electromagnetic compatibility - Requirements and tests
Performance requirements	EN 1060-1:1995+A2:2009 Non-invasive blood pressure Part 1: General requirements EN 1060-3:1997+A2:2009 Non-invasive blood pressure Part 3: Supplementary requirements for electromechanical blood pressure measuring system
Clinical investigation	EN 1060-4: 2004 Automatic Blood Pressure Monitor overall system Interventional accuracy of the testing process
Usability	EN 60601-1-6: 2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability EN 62366: 2008 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

♥ 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)