



User Manual

Blood Pressure Monitor

Arm Type

MATRIX 100



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GENERAL DESCRIPTION

Thank you for selecting TRANSTEK arm type blood pressure Monitor (TMB-1491-A). The monitor features blood pressure measurement and pulse rate measurement. The design provides you with two years of reliable service. Reading taken by the TMB-1491-A 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:
- 60×40.5 mm Bright LCD display
 - One record
 - 3rd technology: 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 - Waste 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"		Symbol for "Authorised Representative in the European Community"

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.

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.

To avoid measurement errors, carefully read this manual before using the product.

The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The operator shall not touch output of batteries 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 when using the AC adaptor.

The user must check that the equipment functions safely and see that it is in proper working condition before being used.

Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE.

Otherwise, it may cause damage to the unit or danger to the user/patients.

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 5:2009-10993 and ISO 10:2010-10993. It will not cause any potential allergic reaction or contact injury.

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.

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.

This device is contraindicated for any female subject who may be suspected of, or is pregnant.

Besides provided inaccurate readings, the affects of this device on the fetus are unknown.

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 itspressurization on any wrist where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; Inflating the cuff on the wrist on the side of a mastectomy.

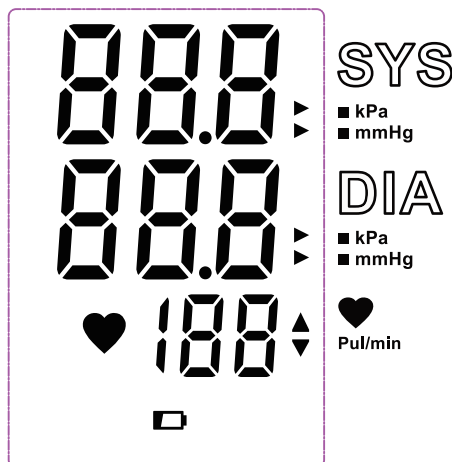
Do not apply the cuff over a wound, otherwise it can cause further injury.


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 Using it in case to result in prolonged impairment of the circulation of the blood of the PATIENT.

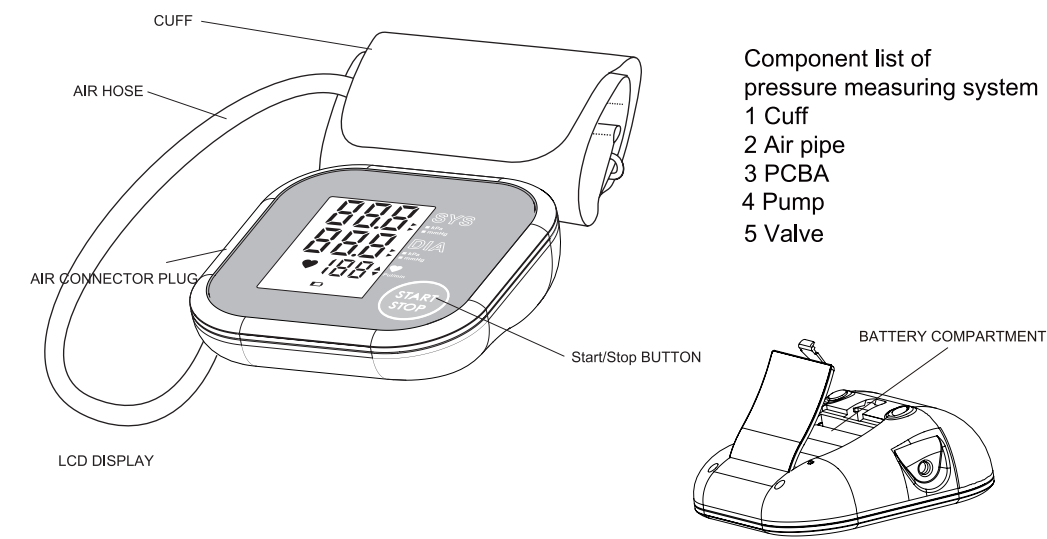
Don't kink the connection tube, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.

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
♥	Heartbeat	Heartbeat Detection during the measurement
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

MONITOR COMPONENTS



LIST

- 1.Blood Pressure Monitor (TMB-1491-A)
- 2.Cuff (Type BF applied part) (22~32cm or 22~42cm)
3. 4×AAA alkaline batteries
- 4.User manual

MEASUREMENT PRINCIPLE

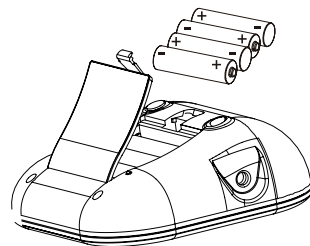
This product uses the Oscillometric Measuring method to detect blood pressure.

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%.

INSTALLING AND REPLACING THE BATTERIES

- Slide off the battery cover.
- Install the batteries by matching the correct polarity, as shown.
(Always select the authorized / specified battery: Four AAA-size alkaline batteries).
- Replace the cover.



Replace the batteries whenever the below happen

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

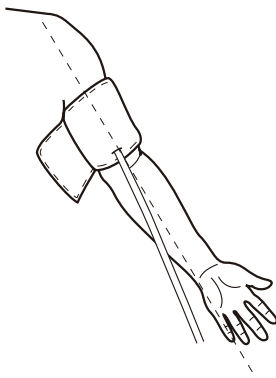


CAUTION

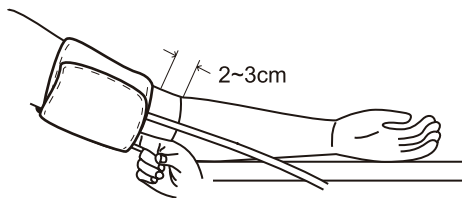
- Remove batteries if the device is not likely to be used for some time.
- The old battery is harmful to the environment, so please disposal with other daily trash
- Remove the old battery from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may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

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

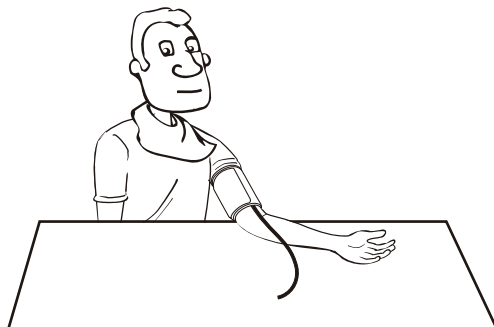


3.Sit comfortably with your tested arm resting on a flat surface.

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.

- 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.

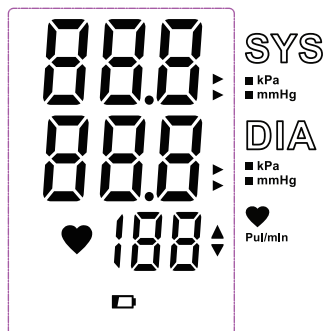


START THE MEASUREMENT

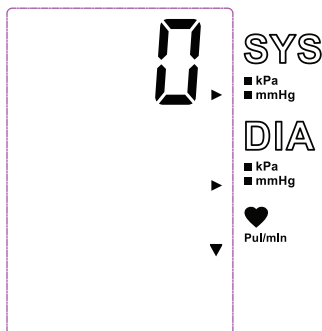
1.When the monitor is off, press the "START/STOP" button to turn on the monitor, and it will finish the whole measurement .



LCD display

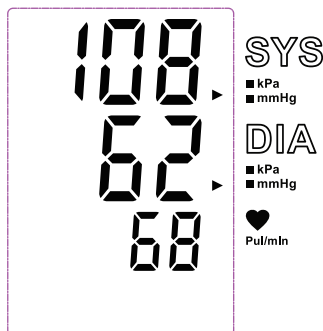
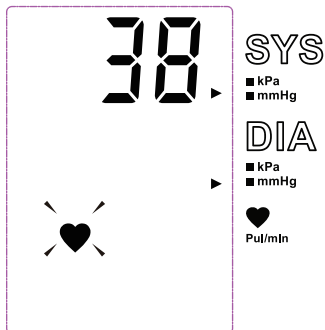


Adjust the zero.



Inflating and measuring.

Display and save the result.



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



TIPS FOR MEASUREMENT

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



Within 1 hour
after dinner or drinking



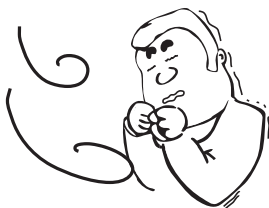
Immediate measurement
after tea, coffee, smoking



Within 20 minutes
after taking a bath



When talking or moving your fingers



In a very cold environment



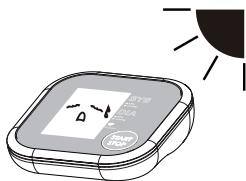
When you want to discharge urine



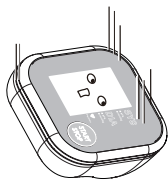
MAINTENANCE

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

instructions.



Put in a dry place and avoid the sunshine



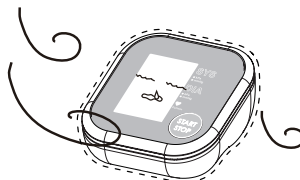
Avoid the intense shaking and collision



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

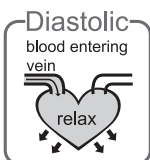
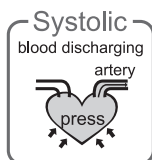


Do not attempt to clean the reusable cuff with water and never immerse the cuff in water.

- If you have any problems with this device, such as setting up, maintaining or using, please contact with SERVICE PERSONNEL of M.FEINGERSH & CO LTD. Don't open or repair the device by yourself.
- Please report to M.FEINGERSH & CO LTD. if any unexpected operation or events occur.
- Cleaning: Dust environment may affect the performance of the unit. Please use the soft cloth to remove the dirt of the device and cuff before and after use.
- Disposal: Degraded sensors or loosened electrodes may degrade the unit's performance or even cause other problems. Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.


WHAT ARE SYSTOLIC PRESSURE AND DIASTOLIC PRESSURE?

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

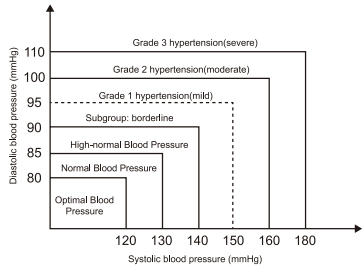


WHAT IS THE STANDARD BLOOD PRESSURE CLASSIFICATION?

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

**CAUTION**

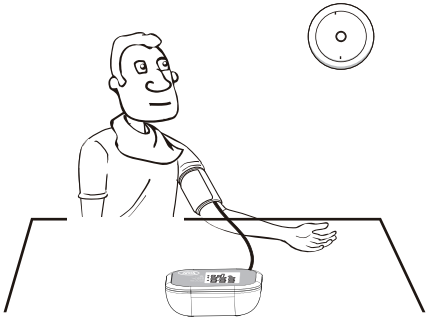
Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Kindly note that only a physician could tell whether your blood pressure value has reached a dangerous point.



Level Blood Pressure (mm Hg)	Optimal	Norm		Hypertension		
				G1	G2	G3
SYS	<120	121-130	131-140	141-160	161-180	≥180
DIA	<80	81-85	86-90	91-100	101-110	≥110

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?

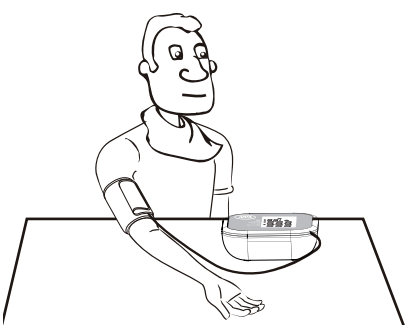
The blood pressure is different even during 24 hour because of the weather, emotion, exercise etc, specially the "white coat" in hospital which makes the results are higher than the ones at home.

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 3-2 times before beginning.
- Advice: adjust yourself for 5-4 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
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.	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
Display mode	Digital LCD V.A.60×40.5mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0kpa - 40kpa (0mmHg~300mmHg) Measurement pressure: 4kPa-34kPa (40mmHg-230mmHg) pulse value: (40-199) beat/minute
Accuracy	Pressure: 5°C-40°Cwithin±0.4kpa(3mmHg) pulse value:±5%
Normal working condition	Temperature:5°C to 40°C Relative humidity ≤85% Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20°C-60°C Relative Humidity 10%-93% Atmospheric Pressure: 50-106 kPa
Measurement perimeter of the upper arm	About 22cm~32cm or 22cm~42cm
Net Weight	Approx.175g(Excluding the dry cells)
External dimensions	Approx.110×110×40mm
Attachment	4×AAA alkaline batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP22
Software Version	V01

WARNING: No modification of this equipment is allowed.

COMPLIED EUROPEAN STANDARDS LIST

Risk Management	EN/ISO 14971:2012
Labeling	EN 1:2012-15223
User Manual	EN 1041:2008
General Requirements for Safety	EN 1:2006-60601/AC2010 EN 11:2010-1-60601
Non-invasive Sphygmomanometers General Requirements	EN +1:1995-1060A2:2009 EN +3:1997-1060A2:2009 EN 4:2004-1060
Electromagnetic Compatibility	EN 2:2007-1-60601
Software Lifetime	EN 62304:2006/AC:2008
Usability	EN 6:2010-1-60601 EN 62366:2008

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 $d=3,3\text{m}$ away from the equipment.

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