TRANSTEK

Guangdong Transtek Medical Electronics Co., Ltd.

广东乐心医疗电子股份有限公司

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Celia Li		

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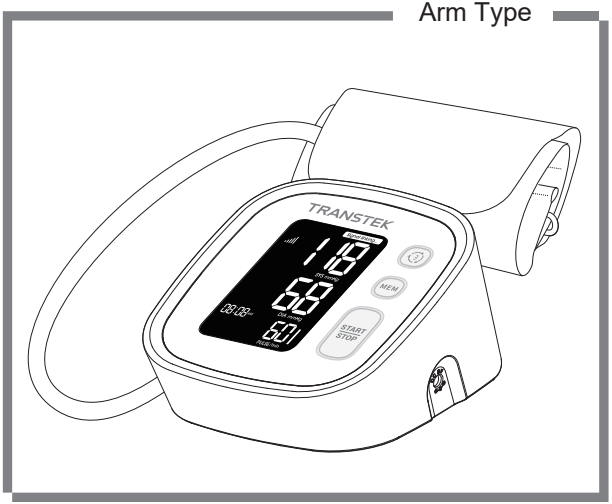
version: A/0

TRANSTEK

User Manual

Blood Pressure Monitor BB1597-G

Arm Type



- Thank you very much for selecting TRANSTEK Blood Pressure Monitor Model: BB1597-G.
- Please read the user manual carefully and thoroughly so as to ensure the safe usage of this product,Keep the manual well for further reference in case you have problems.

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

version:A/0

Table of Contents

♥ General Description

Thank you for selecting TRANSTEK blood pressure monitor (BB1597-G). The monitor features blood pressure measurement, pulse rate measurement and the result storage.

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:

- 74.6mm×50.6mm Digital LCD display
- E-MTC wireless communication
- Three consecutive measurements
- Maximum 60 records

♥ Indications for Use

This Blood Pressure Monitor is intended for use in measuring blood pressure and pulse rate in patients with arm circumferences from 16 ~ 36 cm (about 6⅓″-14⅛″), 22 ~ 42 cm (about 8¾″-16½″), 22 ~ 45 cm (about 8¾″-17¾″) or 40 ~ 52cm (about 15 ¾″ ~ 20 ½″).
Cuff model AC1636-01, arm circumference range is 16 ~ 36cm (about 6⅓ ″-14⅛″), which is intended for children older than 3 years old or adults without conditions of diabetes, pregnancy, or pre-eclampsia.
Cuff model AC2245-021, arm circumference range is 22 ~ 45cm(about 8¾″-17¾″), which is intended for adult population or those who with conditions of diabetes, pregnancy, or pre-eclampsia.
Cuff model AC2242-41 and cuff model AC4052-04, arm circumference range are 22 ~ 42cm (about 8¾″-16½″), and 40 ~ 52cm(about 15 ¾″ ~ 20 ½″) respectively, which are intended for adults without conditions of diabetes, pregnancy, or pre-eclampsia.
It is intended indoor use only.

♥ 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 atmosphere pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

♥ Safety Information

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

	Recyclable		Type BF applied part
	Direct Current	SN	Serial Number
	Date of manufacture		Manufacturer
	Class II Equipment		For indoor use only
	Temperature limit		Humidity limitation
	Atmospheric pressure limitation		
	Refer to instruction manual/booklet To signify that the instruction manual/ booklet must be read. Note: The background color of the symbol is blue.		
MR	MR Unsafe To identify an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.		
	Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.		
	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.		

Precaution

* **Blood Pressure Monitor is intended to be operated by adults, including medical staffs and lay persons. Adult patients could also be intended users or operators.**
* This device is intended for indoor, home use and is not intended for self-use in public areas.
* This device is portable, but it is not intended for use during patient transport.
* This device is not suitable for continuous monitoring during medical emergencies or operations.
* This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm, or for any purpose other than obtaining a blood pressure measurement.
* This device is for patients who are at or over 3 years old. Do not use this device on neonates or infants.
* Consult with your physician before using this monitor if you suffer from the following conditions: common arrhythmias such as premature ventricular beats or atrial fibrillation; peripheral arterial disease, implantation with electrical devices; undergoing intravascular therapy; arteriovenous shunt or mastectomy. Please note that any of these conditions may affect measurement readings, in addition to patient motion, trembling or shivering.
* If you are taking medication, consult your physician to determine the proper time to measure your blood pressure.
* This device may be used only for the intended use described in this manual, the manufacturer shall have no liability for any incidental, consequential, or special damages caused by misuse or abuse.
* Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
* The device may require up to 30 minutes to warm up / cool down from the minimum/ maximum storage temperature before it is ready for use.
* The blood pressure monitor, its adapter, and the cuff are suitable for use within the patient environment.
* Do not wash the cuff in a washing machine or dishwasher !
* The device contains sensitive electronic components. To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies may cause interference that may affect the accuracy of measurements. A minimum distance of 1 foot (30 cm) should be kept from such devices during a measurement.
* Please choose the appropriate cuff according to your arm circumference and physical health.

⚠ Caution

* Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out byauthorized service centers.
* It is recommended that the performance should be checked after repair, maintenance, and every two years of use, by retesting the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHg and 200 mmHg). Please contact manufacturer or distributor for authorized service personnel.
* Store your device, cuff and adapter in a clean and dry place, protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on it.
* Make sure the rubber tube of the cuff is not squeezed, stretched, or kinked during storage.
* Dispose of accessories, detachable parts, and the device according to the local guidelines.

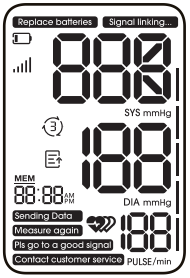
Warning

* **DO NOT self-diagnose the measurement results and start treatment by yourself. The measurement results given by this device is not a diagnosis. ALWAYS consult your doctor for evaluation of the results and treatment.**
* **DO NOT adjust medication based on readings from this blood pressure monitor. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high blood pressure.**
* **DO NOT** apply the cuff on an arm that has an intravenous drip or a blood transfusion attached.
* **DO NOT** kink, fold, stretch, compress, or otherwise deform the tube during measuring, as the cuff pressure might continuously increase, which could prevent blood flow and result injury.
* Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.
* **DO NOT** apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.
* **DO NOT** place the cuff on the arm of a person whose arteries or veins are undergoing medical treatment, i.e. intra-vascular access or intra-vascular therapy or an arteriovenous (A-V) shunt, which could disrupt blood circulation and cause injuries.
* **DO NOT** place the cuff on the arm on the same side of a mastectomy (especially when lymph nodes have been removed). it is recommended to take measurements on the unaffected side.
* **DO NOT** wrap the cuff on the same arm to which another monitoring device is applied. One or both devices could temporarily stop functioning if you try to use them at the same time.
* Warning: Please check (for example, by observation of the limb concerned) that the operation of the device does not result in prolonged impairment of patient blood circulation.
* Warning: On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, loosen and remove the cuff immediately. Prolonged high pressure applied to the arm (cuff pressure >300 mmHg or constant pressure >15 mmHg for more than 3 minutes) might lead to bruising and discolored skin.
* **DO NOT** use this device with high-frequency (HF) surgical equipment at the same time.
* This device is not used in conjunction with oxygen rich environments, not intended for use with flammable anaesthetics, not intended for use in conjunction with flammable agents.
* Excessive cuff tube lengths could cause strangulation if you don't manage them properly.
* **DO NOT** touch output of the batteries/adapter and the user simultaneously.
* The power cord is considered the disconnect device for isolating this equipment from supply mains. **DO NOT** position the equipment so that it is difficult to reach or disconnect.
* **DO NOT** use this device if you are allergic to polyester, nylon, or plastic.
* Only use accessories approved by manufacturer. Using unapproved accessories might cause damage to the unit and injure users.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the Power button immediately to release the air from the cuff.
* **DO NOT** use the device while under maintenance, or being serviced.
* Sensor degradation or looseness may reduce performance of device or cause other problems.
* The air tube poses a risk of strangulation. Furthermore, the small parts of product and batteries present a choking hazard if swallowed. They should therefore always be kept away from infants/children.

Notice

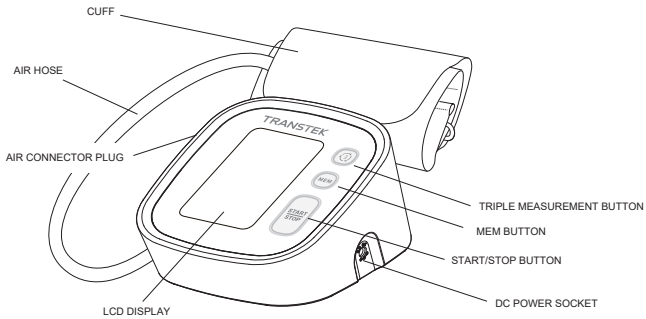
* You can use this device to take your own measurement, no third-party operator is required.
* Adapter is specified as a part of ME EQUIPMENT.
* At the request of authorized service personnel, circuit diagrams, component part lists, descriptions, and calibration procedures will be made available by the manufacturer or distributor.
* The expected lifetime of the cuff may vary by the frequency of washing, skin condition, and storage state.
* Please report to the manufacturer and the competent authority of the Member State / the FDA in which you are established about any serious incident that has occurred in relation to this device.

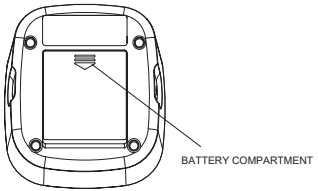
♥ LCD display signal



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic pressure	High blood pressure
DIA	Diastolic pressure	Low blood pressure
PULSE/min	Pulse display	Pulse in beats per minute
mmHg	mmHg	Measurement Unit of the blood pressure
+ Replace batteries	Low battery	Indicate the battery is too low, need to replace batteries.
88:88 AM PM	Current Time	Hour : Minute
	Irregular pluse rate	Appears when an iIrregular pulse rate is detected during a measurement. Refer to page 17 for more information.
	Pluse rate	Flashes when the pulse rate is detected during the measurement.
	Blood pressure level indicator	Indicate the blood pressure level.
	Network Signal indication	Indicates the network signal situation in the communication process.
	Three consecutive measurements	Indicates the current measurement mode is three consecutive measurements.
	Data pending to transmit icon	Appears when the data transmission failed. Up to 60 measurements can be temporarily saved on the device and send to your account when the Cellular internet is available.
MEM	Memory Query	Indicate it is in the memory mode and which group of memory it is.
Signal linking... Sending Data Measure again Pls go to a good signal Contact customer service	Warning messages	refer to page 19 for more information.

♥ Monitor Components





♥ List

1. Blood Pressure Monitor (BB1597-G)

2. Cuff (Type BF applied part)

Upper arm cuff:16-36cm or
Upper arm cuff:22-42cm or
Upper arm cuff:22-45cm or
Upper arm cuff:40-52cm.

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

3. 4×AA batteries

4. AC Adapter(Optional!) (BLJ06L060100P-U)

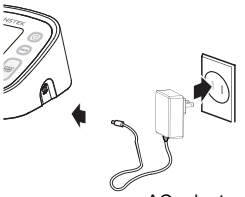
5. User manual

♥ The Choice of Power Supply

1. Battery powered mode:
   6V DC 4×AA batteries
2. AC adapter powered mode:
   6V ⎓ 1A(Optional!)

(Please use the AC adapter which authorized by the manufacturer!).

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



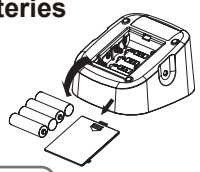
AC adapter

⚠ CAUTION

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



Replace the batteries whenever the below happens

- The Replace batteries shows
- The display is dim
- The display does not light up.

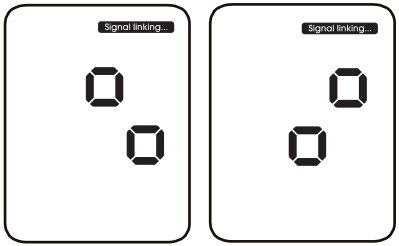
⚠ CAUTION

- 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.

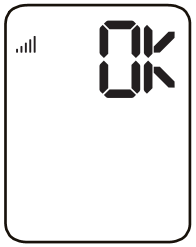
♥ Setting up

1. Every time when you insert or replace batteries into the device, it will start network connection, the device will try to connect to the network for 10 minutes.

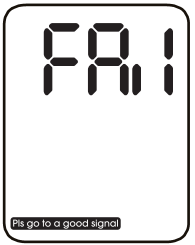
   As shown on the right, it indicates that it is looking for a network.



2. If the connection is successful, the LCD will display " OK ", and it will turn off after 10 seconds automatically.



3. If the device fails to connect the network within 10 minutes, it will dispaly " FAIL+ Pls go to a good signal " and then turn off automatically.



♥ Applying the cuff

Only use a cuff that has been approved by the manufacturer for this device model. Before use, please confirm if it fits your arm circumference.

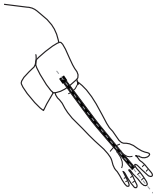
Choosing for cuff:

Cuff model AC1636-01, arm circumference range is 16 ~ 36cm (6 1/3 ~14 1/5 inch), which is intended for children older than 3 years old or adults without conditions of diabetes, pregnancy, or pre-eclampsia.

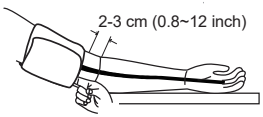
Cuff model AC2245-021, arm circumference range is 22 ~ 45cm (8 ¾ ~ 17 ¾ inch) , which is intended for adult population or those who with conditions of diabetes, pregnancy, or pre-eclampsia.

Cuff model AC2242-41 and cuff model AC4052-04, arm circumference range are 22 ~ 42cm (8 ¾ ~ 16 ½ inch), and 40 ~ 52cm (15 ¾ ~ 20 ½ inch) respectively, which are intended for adults without conditions of diabetes, pregnancy, or pre-eclampsia.

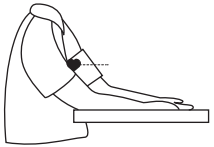
1. Remove all jewelry, such as watches and bracelets from your left arm.
   Note: If your doctor has diagnosed you with poor circulation in your left arm, use your right arm.



2. Roll or push up your sleeve to expose the skin. Make sure your sleeve is not too tight.
3. Hold your arm with palm facing up and tie the cuff on your upper arm, then align the air tube toward the center of your arm.
4. Make sure the bottom edge of the arm cuff 2-3 cm (0.8-1.2 inch) above the inside elbow. Then wrap the cuff securely.
   Note: The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.



5. Sit upright in a comfortable chair with your back against the backrest of the chair. Keep your feet flat and your legs uncrossed.
   Place your arm resting comfortably on a flat table. The cuff worn on your arm should be placed at the same level as your right atrium of the heart.



6. Take 5-6 deep breaths and let's start measuring!

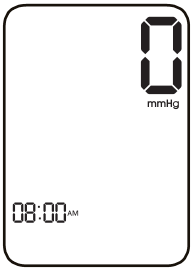
Helpful tips to help ensure an accurate reading

- Take the measurement in a silent room.
- Rest for 5 minutes before a measurement.
- Be relaxed, remain still and DO NOT talk while taking a measurement.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.

♥ Start the Measurement

1. When the monitor is off, press “START/STOP” button to turn on the monitor, and it will finish the whole measurement automatically. (Take User 1 for example.)

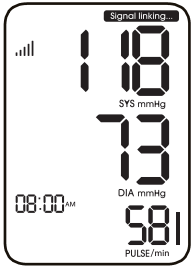
Adjust the zero.



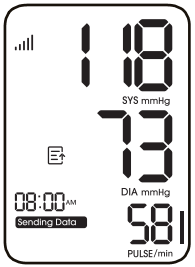
Inflating and measuring.

2. After finishing the measurement, start the web search work and upload the measurement results.

Start the web search



Display and save the measurement results.

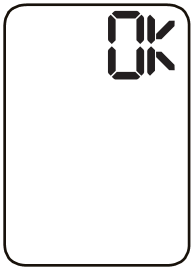


(The data is pending to be transmitted.)

If successful, the symbol " " and " Sending Data "will disappear , and the LCD will display " ".

Press any button to turn off the device, otherwise it will power off automatically.

Data upload complete.



Tips:

1. You can press any button at any time to stop measuring during the process of measurement.

2. 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".

3. If an irregular pluse rate was detected during the reading, the regular pluse rate detector indicator will appear on the display. See page 17 for more information on the irregular pluse rate detector feature.

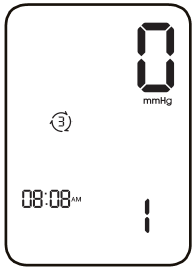
♥ Three consecutive measurements

1. When the monitor is off, press the "TRIPLE MEASUREMENT" BUTTON, it will enter triple measurement mode standby state (10 seconds no operation to exit).

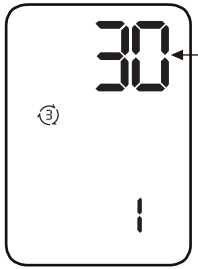
2. Press the "START/STOP" BUTTON to start three measurements. (Take User 1 for example.)

3. When the LCD displays 1, the first measurement starts. After the measurement is completed, the device automatically deflates. The display does not show the measurement result and starts a 30-second countdown, then starts automatically second measurement.

Start the first measurement

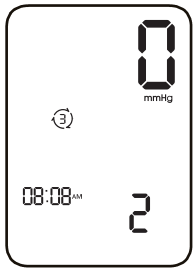


Measurement completed

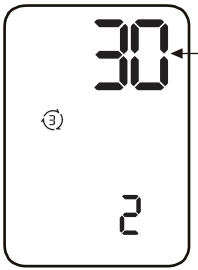


4. When the LCD displays 2, the second measurement starts. After the measurement is completed, the device automatically deflates. The display does not show the measurement result and starts a 30-second countdown, then starts automatically third measurement.

Start the second measurement



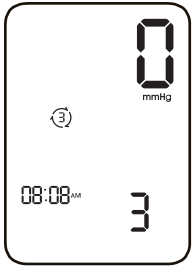
Measurement completed



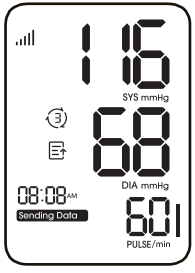
5. When theLCD displays 3, the third measurement starts.

After the three measurements are completed, it display the average of the three measurement results and uploads the data.

Start the third measurement



Display the average of three measurements and upload the data

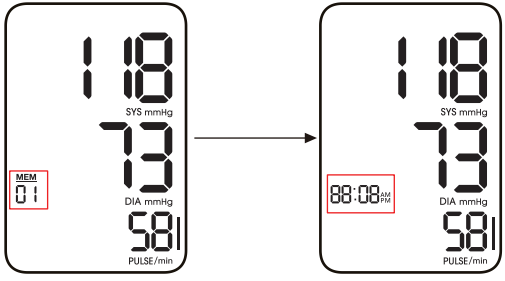


Data upload complete.

♥ Recall the Records

1. When the monitor is off, press the “MEM” button, the LCD will display the latest record.

（The LCD will displays the number of memory groups and displays the time after 2 seconds.）



2. Press the “MEM” button again to display the next record.

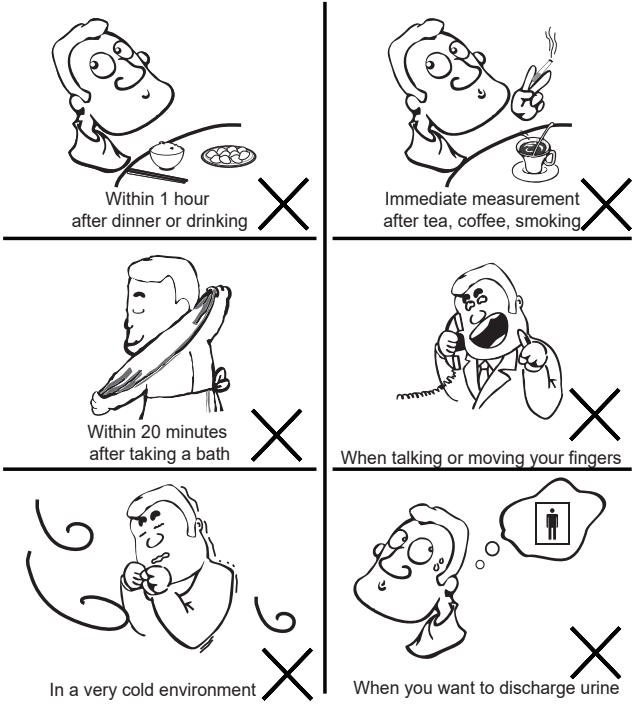
3. Press the START/STOP button to turn off the monitor, otherwise it will power off automatically after about 10s.

Note

- 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.

♥ 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.

1. Cleaning Process:

Step 1: Make sure to switch off and unplug the device prior to cleaning.
Step 2: Use a soft cloth wetted with soapy water to clean the cuff first, and then use a soft cloth wetted with clear water to remove residual soap until there is no visible residual contaminants. Attention shall be paid to avoid liquid invasion into the cuff.
Step 3: Use a dry soft cloth to wipe the cuff, in order to remove residual moisture.
Step 4: Dry the cuff at a well-ventilated place after cleaning.

2. Disinfection Process:

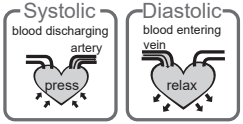
Step 1: Make sure to switch off and unplug the device prior to disinfection.
Step 2: Use a soft cloth wetted with 70% isopropanol to disinfect the cuff for about 3 minutes. Attention shall be paid to avoid liquid invasion into the cuff.
Step 3: Use a clean dry cloth or towel to wipe off the disinfectant until there is no visible residue.
Step 4: Dry the cuff at a well-ventilated place after disinfection.

- **Suggestion:**

Frequency of Cleaning and Disinfection:
For single patient multiple use, it's recommended to clean the device surface once a month or whenever it's necessary.
For multiple patient multiple use, it's recommended to clean the device every time before and after usage. Maintenance procedures shall be taken as per instruction.

♥ 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).

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
Elevated	120-129	and	less than 80
High Blood Pressure (Hypertension) Stage 1	130-139	or	80-89
High Blood Pressure (Hypertension) Stage 2	140 or higher	or	90 or higher
Hypertensive Crisis (Consult your doctor immediately)	Higher than 180	and/or	Higher than 120

⚠ CAUTION

Please consult a physician if your measuring result falls outside the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

♥ Irregular pluse rate Detector

An irregular pluse rate is detected when a pluse rate rhythm varies while the device is measuring systolic pressure and diastolic pressure. During each measurement, blood pressure monitor will keep a record of all the pulse intervals and calculate the average value of them. If there are two or more pulse intervals , the difference between each interval and the average is more than the average value of ±25% , or there are four or more pulse intervals ,the difference between each interval and the average is more than the average value of ±15%, then the irregular pluse rate symbol will appear on the display with the measurement result.

⚠ CAUTION

The appearance of the IPR icon indicates that a pulse irregularity consistent with an irregular pulse rate 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 irregular pulse rate detector results cannot be used directly for clinical judgement. Please seek medical advice from professionals before making any medical decisions.

♥ 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:

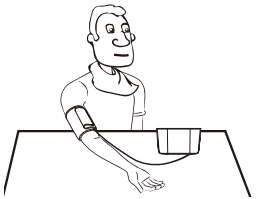
If the cuff is tied properly.
If the cuff is too tight or too loose.
If the cuff is tied on the upper arm.
If you feel anxious.

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.
		Adapter is inserted incorrectly.	Insert the AC adapter correctly.
Low batteries	Display is dim or show Replace batteries	Batteries are low.	Replace with new batteries
High battery	bAtH shows	Battery voltage is too high	Please disconnect the power adapter.
Error message	E 1 + Measure again shows	The cuff is too tight or too loose.	Refasten the cuff and then measure again.
	E 2 + Measure again shows	The monitor detected motion while measuring.	Movement can affect the measurement.Relax for a moment and then measure again.
	E 3 + Measure again shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E 4 + Measure again shows	Cannot calculate blood pressure	Relax for a moment and then measure again.
	E 5 + Pls go to a good signal shows	Abnormal communication with server or fails to transmit data.	Try a place with better signal, or contact customer service.
	E 6 + Pls go to a good signal shows	Cannot connect to the Internet.	Contact customer service.
	E 8 + Measure again shows	SIM card detection failed (detected 3 times).	Turn off monitor and measure again. If E8 still appears on the display, please contact the retailer or our customer service.
	EEx + Measure again, shows on the display.	Hardware error (x can be some digital symbol, such as 1, 2, 3, etc.)	Turn off monitor and measure again. If EEx still appears on the display, please contact the retailer or our customer service.
	oUt shows	Out of measurement range	Relax for a moment and then measure again.

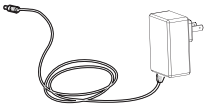
Power supply	Battery powered mode: 6VDC 4×AA batteries AC adapter powered mode: 6V ⎓ 1A (Optional) (Please only use the recommended AC adapter model).
Display mode	Blue LCD with white backlight V.A.73mm×49mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg Measurement pressure: SYS: 60mmHg~230mmHg DIA: 40mmHg~130mmHg Pulse value: (40-199)beat/minute
Accuracy	Pressure: 5℃-40℃within±3mmHg 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 An atmosphere pressure range of: 500hPa to 1060 hPa
Measurement perimeter of the upper arm	About 16~36cm, 22~42cm, 22~45cm or 40~52cm
Weight	Approx.274g(Excluding the batteries and cuff)
External dimensions	Approx.118mm×126mm×72mm
Attachment	4×AA batteries, adapter, 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.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adapter Powered Mode: Class II ME Equipment
Software Version	A01

Expected Lifetime	Device: 2 years or 10,000 measurements (may vary based on usage conditions) Cuff: 10,000 times Alkaline battery: About 200-300 times Adapter: About 20,000 hours
Types of use/reuse	Multiple patient multiple use

WARNING: No modification of this equipment is allowed.

♥ Authorized Component

Please use the TRANSTEK authorized adapter. (Optional!)



Adapter
Model：BLJ06L060100P-U
Input：AC 100-240V
50/60Hz 0.2A Max
Output：6V ⎓ 1000mA

♥ Contact Information

For more information about our products, please visit www.transtekcorp.com.

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

♥ FCC Statement

FCC ID: OU9BB-1597-G

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 equipment should be installed and operated with minimum distance 20cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC Responsible Party
Name: MIO LABS INC.
Address: #1023, ZGC Innovation Center, 4500 Great America Pkwy, Santa Clara, CA 95054
Telephone: 301-910-0529
E-mail: mio@transtekcorp.com

♥ EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments.

Warning: Don't be near the active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description:

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected lifetime.

2. Guidance and manufacturer's declaration-electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [B]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not Applicable 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 250 / 300 cycle	0% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 250 / 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communicati-ons equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM ± 5k Hz deviation 1 kHz sine	2	0.3	28	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	745							
	780							
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
	5500							
	5785							

♥ Specifications for 4G

Specifications for 4G		
E-MTC	Supporting band:	Cat-M1: B2/4/12/13/25
	Transmitted frequency range	1850—1910MHz, 1710—1755MHz, 699—716MHz, 777—787MHz, 1850—1915MHz
	Transmitted power	20±2dBm
	Throughput	588~1119 kbps
	Latency	≤21ms
	Jitter	≤21ms
	PER	＜5%
	Data Integrity	Data shall be transmitted correctly and completely
	Accessibility	Accessibility is high since 4G is broadband

Remark:

1.The Quality of Service (QoS) is considered as KPIs here.

2. For the Blood Pressure Monitor，the E-MTC is used to transmit the control data between the EUT and the controller,the manufacture considered 375~1119 kbps is a suitable throughput for the usage

3.The PER of the wireless system is normally less than 1%, for Semi-anechoic chamber, we considered the PER cannot be greater than 10%.

4. Use the wireless module which the EUT used as the test model,instead the EUT.

Warning

Failure to comply with the following warnings may cause cybersecurity issues.

DO NOT casually use the blood pressure monitor for others, as it may lead to leakage of personal measurement data.

DO NOT connect the blood pressure at places with poor network or wireless connectivity. as it may interrupt data upload and lead to deficient data.