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TRANSTEK

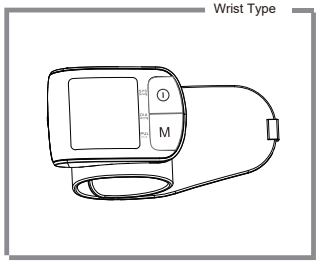
Version:1.0

TRANSTEK

# User Manual

**Arm Blood Pressure Monitor**

**Model: TMB-2085**




Thank you for selecting Transtek Blood Pressure Monitor. Please read the user manual carefully and thoroughly so as to ensure the safe usage of this product. Keep this manual for further reference in case any issues arise.

## CATALOGUE

## ♥ General Description

This product features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.
Readings taken by this blood pressure monitor TMB-2085 is equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.
This manual contains important safety and care information, and provides step by step instructions for using this blood pressure monitor. Read the manual thoroughly before using this product.
Features:

- Systolic blood pressure
- Diastolic blood pressure
- Pulse rate
- 120 records for one user

## ♥ Indications for Use

This Transtek Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate with a wrist circumference ranging from 13.5 cm to 21.5 cm or 13.5 cm to 23 cm. It is intended for indoor, adult use only.





## ♥ Contraindications

1.The device is not suitable for use on the women who are or may be pregnant.
2.The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators.

## ♥ Measurement Principle

This product uses the Oscillometric Measuring Method to detect blood pressure. Before every measurement, the unit establishes a “zero point” equivalent to the atmospheric pressure. Then it starts inflating the cuff. Meanwhile, the unit detects pressure oscillation generated by beat-to-beat pulsatile, which is used to determine the systolic pressure and diastolic pressure as well as 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.

| | | | |
|---|---|---|---|
|  | Symbol for “THE OPERATION GUIDE MUST BE READ” |  | Symbol for “TYPE BF APPLIED PARTS” |
|  | Symbol for “MANUFACTURE DATE” |  | Symbol for “ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice” |
|  | Symbol for “MANUFACTURER” | | |
|  | Symbol for “SERIAL NUMBER” |  | Symbol for “DIRECT CURRENT” |
|  | Symbol for “RECYCLE” |  | Caution: These notes must be observed to prevent any damage to the device. |





### ⚠ CAUTION

* This device is intended for adult use in homes only.
* The device is not suitable for use on neonatal patients, pregnant women,patients with implanted, electronical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses.
* The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
* The device is not intended for patient transport outside a healthcare facility.
* The device is not intended for public use.
* This device is intended for no-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the wrist or for functions other than obtaining a blood pressure measurement.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure.Do not begin or end medical treatment without asking a physician for treatment advice.
* If you are taking medication,consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.
* Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
* When the device is used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result.
* Warning: 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.

## ⚠ CAUTION

*On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure ＞ 300mmHg or constant pressure ＞ 15mmHg for more than 3 minutes) applied to the wrist may lead to an ecchymosis.
*Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measurement, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.
* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.
* To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
* This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
* Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
* This unit is not suitable for continuous monitoring during medical emergencies or operations.Otherwise, the patient's wrist and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
* When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
* This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
*This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.
* The maximum temperature that the applied part can be achieved is 42.5℃ while the environmental temperature is 40℃.
* 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.
* Warning: No servicing/maintenance while the ME equipment is in use.
* The patient is an intended operator.





## ⚠ CAUTION

* The patient can measure data and change batteries under normal circumstances and maintain the device and its accessories according to the user manual.
* To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* The blood pressure monitor and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
* During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensization or irritation reaction.
* If you experience discomfort during a measurement, such as pain in the wrist or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your wrist.
* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressure reaches 40 kPa (300 mmHg), detach the cuff from the wrist and press the START/STOP button to stop inflation.
* Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.Do not wash the cuff in a washing machine or dishwasher!
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
* Please dispose of ACCESSORIES, detachable parts,and the ME EQUIPMENTaccording to the local guidelines.
* Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions,etc., to assist to service personnel in parts repair.
* The operator shall not touch output of batteries and the patient simultaneously.

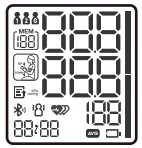
CAUTION

* Cleaning :Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
* The device doesn't need to be calibrated within two years of reliable service.
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Transtek. Don't open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
* Please report to Transtek if any unexpected operation or events occur.
* Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.
* At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
* This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
* Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the MANUFACTURER from the 80MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.
* Please use ACCESSORIES and detachable parts specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
* There is no luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
* Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.





## ♥ LCD Display Symbol



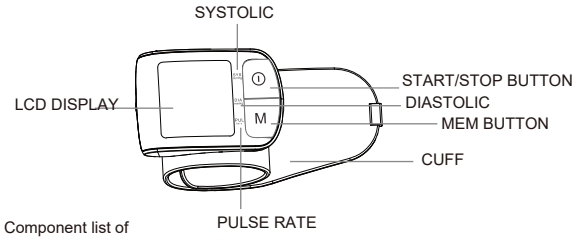
| SYMBOL | DESCRIPTION | EXPLANATION |
|---|---|---|
| SYS | Systolic blood pressure | High pressure result |
| DIA | Diastolic blood pressure | Low pressure result |
| Pulse /min | Pulse | Pulse/minute |
| 1 2 G | User ID | User 1/2/Guest |
| 88:88 | Current Time | Time(year:month:day:hour:minute) |
| | Heartbeat | Heartbeat dectetion during measurement |
| | Hand shaking | Hand shaking makes results inaccurate |

| SYMBOL | DESCRIPTION | EXPLANATION |
|---|---|---|
| | Battery Indicator | Indicate the current battery |
| | Irregular heartbeat | Irregular heartbeat |
| | Data transmitting | Data is transmitting |
| | Postion | Adjust your hand to correct position |
| | Blood pressure level | Indicate blood pressure level |
| | Bluetooth icon | The bluetooth icon blinks when the bluetooth is working |
| AVG | Average value | The average value of the latest three groups bood pressure value |
| MEM | Memory Query | Indicate it is in the memory mode and which group of memory it is. |
| kPa mmHg | kPa mmHg | Measurement Unit of the blood pressure |



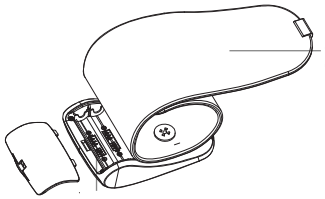


## ♥ Monitor Components




Component list of pressure measuring system:

1. PCBA;
2. Air Pipe;
3. Pump;
4. Valve;
5. Cuff.




## List

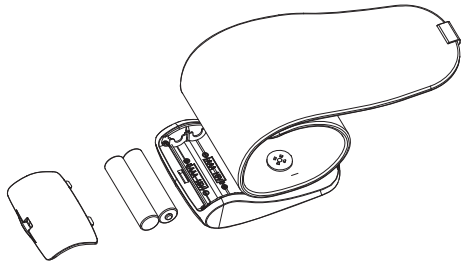
1) Blood Pressure Monitor TMB-2085
2) 2× AAA Batteries
3) User manual





## ♥ Installing and Replacing the Batteries

- Slide off the battery cover.
- Install the batteries as indicated in the battery compartment.
  Always use the correct battery type (2× AAA batteries).
- Replace the battery cover.
  The typical service life of the new and unused batteries
  is about 45 measurements for the operation time is 60s.



Replace the batteries whenever the below happen

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

⚠CAUTION

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



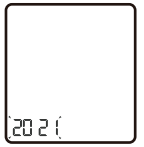


**♥ Setting Date and Time**

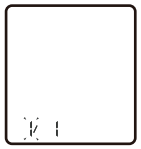
It is important to set the Date and Time before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (Year Range: 2020-2099; Time Format: 24 Hours)

1.When the monitor is off, Long press “MEM” button, the display will show a blinking number representing the [YEAR].


2.Change the [YEAR] by pressing the“MEM” button. Each press “MEM” button will increase the number by one in a cycling manner.



3.When you get the right year, press the “START STOP” button to confirm the entry. The screen will then show a blinking number representing the [MONTH].



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





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

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

7.After confirming the measurement unit, the LCD will display “dOnE” and then the monitor will turn off.

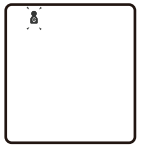

## ♥ Set the User ID

Before you start the measurement, please set your desired user ID.

1.When the blood pressure monitor is off, hold press “START/STOP” button and then the user ID shows. Then press “MEM” button to switch the user ID between user A, user B and Guest mode.



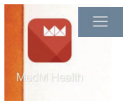




2.Press “START/STOP” button to confirm user ID , the display will show “User ID + dOnE” and then the monitor will turn off.

## ❤ Install the App and Pair-Up

・Download the Transtek Health app from APP Store or Google Play.
・Install the APP, and register an account.










・Click ☰ ,click “My setting”, choose the device and then bind the device and app


### ♥ Search your test information

·After binding the app, back to the beginning page and click “Blood Pressure” to search your test information.







**Bluetooth Module No.:** LS51802
**RF Frequency Range:** 2402 MHz to 2480 MHz
**Output Power Range:** ≤0 dBm
**Supply Voltage:** 1.8-3.6 V
**Transmitting Distance:** 10 meters

List of compatible devices:
For iOS devices:
The operating system must be iOS 11.0 or more.
For Android devices
The operating system must be Android 8.0 or more

### ⚠ CAUTION

- Interference may occur in the vicinity of equipment marked with the following symbol . And TMB-2085 may interfering vicinity electrical equipment.
- Sensitive people, including pregnant women pre-eclamptic and those who implanted medical electronic instruments, should avoid using the unit whenever possible.
- Keep the monitor at least 20 centimeters away from the human body (especially the head) when the data after transmission is proceeding measurement.
- To enable the data transmission function, this product should be paired to Bluetooth end at 2.4 GHz.

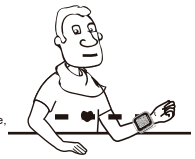
How to mitigate possible interference?

1.The range between the device and BT end should be reasonably close, from 1 meter to 10 meters. Please ensure no obstacles between the device and BT end so as to obtain quality connection and to lower the RF output range.

2. To avoid interference, other electronic devices (particularly those with wireless transmission / Transmitter) should be kept at least 1 meter away from the monitor.

## ♥ Tie the Cuff

1. Remove all accessories (watch, bracelet,etc) from your wrist. If your physician has diagnosed you with poor circulation in your wrist, use the other one.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your wrist with your palm facing up.
4. Position the edge of the cuff about 1cm~2cm from wrist joints.
5. Fasten the wrist cuff around your wrist, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.
6. Sit comfortably with your tested wrist resting on a flat surface. Place your elbow on a table so that the cuff is at the same level as your heart. Turn your palm upwards. Sit upright in a chair, and take 5-6 deep breaths.
7. 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 wrist supported.
   Rest for 5 minutes before measuring.
   Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
   Take the measurement in a silent room.
   The patient must relax as much as possible and do not move and talk during the measurement procedure.
   The cuff should maintain at the same level as the right atrium of the heart.
   Do not cross your legs and keep your feet on the ground.
   Keep your back against the backrest of the chair.
   For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same wrist, 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 complete the whole measurement automatically.(Take user A for example.)

**LCD display.**

**Adjust to zero.**

**Inflating and measuring.**


**Display and save the measuring result.**

After the measurement was finished, the symbol ᛒ will start blinking, and the data will start transmitting.


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





3. If the data transmits successful, the symbol and ᛒ symblo will disappear, and then the monitor will turn off.

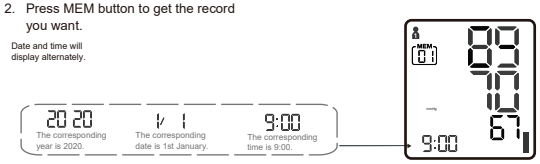

4. If the data transmition fails, the monitor will turn off automatically.

## ♥ Recalling the Records

1. When the monitor is off,press “MEM” button to show the latest record. If there are more than 3 records, it will show the average of latest three records.

2. Press MEM button to get the record you want.

Date and time will display alternately.




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 (120) is dropped from the list.

## ♥ Deleting the Records

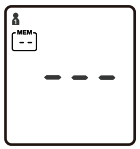
**If you did not get the correct measurement, you can delete all results by following steps below.**





1. When it is in the memory mode, hold pressing “START/STOP” button for 3 seconds, it will display “dEL ALL”+User ID.


3.If there is no record, no numbers will show.




2. Press “MEM” button to confirm deleting, the LCD will display “dEL dOnE” + User ID and then turn off.


Note: To exit delete mode, press START/STOP button before pressing MEM button to confirm any delete commands.

## ♥ Tips for Measurement

**Measurements may be inaccurate if 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

**To obtain the best performance, please follow the instructions below.**

Put in a dry place and
avoid the sunshine

Avoid immersing it in the water.
Clean it with a dry cloth in case.

Avoid shaking and collision.

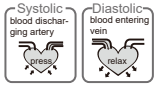
Avoid dusty environment and
unstable temperature surrounding

Use the slightly damp cloth
to remove the dirt.

Avoid washing the cuff

### ♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, blood pressure reaches its maximum value, the highest pressure in the cycle is known as systolic pressure. When the heart relaxes between heartbeats, the lowest blood pressure is 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**

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





### ♥ Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the 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 heartbeat symbol will appear on the display with the measurement result.

**⚠ CAUTION**

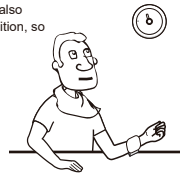
The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

## ♥ Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.

2.If the person takes medicine, the pressure will vary more.

3.Wait at least 3 minutes for another measurement.



## ♥ Why do I get a different blood pressure at home compared to the hospital?

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

## ♥ Is the result the same if measuring on the right wrist?

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

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 wrist.
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.





If any abnormality arises during use, please check the following points:

| PROBLEM | SYMPTOM | CHECK THIS | REMEDY |
|---|---|---|---|
| No power | Display is dim or will not light up. | Batteries are exhausted. | Replace with new batteries |
| | | Batteries are inserted incorrectly. | Insert the batteries correctly |
| Low batteries | +Lo Show on the display | Batteries are low. | Replace with new batteries |
| Error message | E 01 shows | The cuff is not secure | Refasten the cuff and then measure again. |
| | E 02 shows | The monitor detected motion, talking,or the pulse is too poor while measuring. | movement can affect the measurement. Relax for a moment and then measure again. |
| | E 03 shows | The measurement process does not detect the pulse signal. | Loosen the clothing on the wrist and then measure again. |
| | E 04 shows | The treatment of the measurement failed. | Relax for a moment and then measure again. |

## TROUBLESHOOTING

| PROBLEM | SYMPTOM | CHECK THIS | REMEDY |
|---|---|---|---|
| **Error message** | 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. |
| **Warning message** | “out ” shows | Out of measurement range | Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician. |

NOTE: If the product still does not work, contact Transtek Customer Service. Under no circumstance should you disassemble or attempt to repair the unit by yourself.



## SPECIFICATIONS

| | |
|---|---|
| **Power supply** | Battery powered mode: 2x AAA batteries 3V ⎓ |
| **Display mode** | Digital LCD V.A.43 mm x 46 mm |
| **Measurement mode** | Oscillographic testing mode |
| **Measurement range** | Rated cuff pressure:<br>0 mmHg ~ 299 mmHg (0 kPa ~ 39.9 kPa)<br>Measurement pressure:<br>SYS: 60 mmHg ~ 230 mmHg (8.0 kPa ~ 30.7 kPa)<br>DIA: 40 mmHg ~ 130 mmHg (5.3 kPa ~ 17.3 kPa)<br>Pulse value: (40-199)beat/minute |
| **Accuracy** | Pressure: 5°C-40°C within ±3 mmHg (0.4 kPa)<br>Pulse value: ±5% |
| **Working condition** | A temperature range of : +5°C to +40°C<br>A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa<br>An atmospheric pressure range of: 700 hPa to 1060 hPa |
| **Storage & transportation condition** | Temperature: -20°C to +60°C<br>A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa |
| **Measurement perimeter of the wrist** | About 13.5-21.5 cm or 13.5-23.5 cm |
| **Weight** | Approx.102 g (Excluding the batteries) |
| **External dimensions** | Approx.85.7 mm × 60.8 mm × 24.7 mm (Excluding the cuff) |
| **Attachment** | 2x AAA batteries, user manual |

| | |
|---|---|
| **Mode of operation** | Continuous operation |
| **Degree of protection** | Type BF applied part |
| **Device Classification** | Internally Powered ME Equipment |
| **IP Classification** | IP22: The first number 2: Protected against solid foreign objects of 12,5mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure titled up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is titled at any angle up to 15° on either side of the vertical. |
| **Software Version** | A01 |

WARNING: No modification of this equipment is allowed.

## ♥ Contact Information

For more information about our products, please visit www.transtekcorp.com. You can get customer service, usual problems and customer download, Transtek will serve you anytime.

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





## ♥ FCC Statement

**FCC ID: OU9TMB2085-K**

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-- Reorient or relocate the receiving antenna.
-- Increase the separation between the equipment and receiver.
-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-- Consult the dealer or an experienced radio/TV technician for help.
FCC Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

## ♥ Complied Standards List

| | |
|---|---|
| **Risk management** | EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices |
| **Labeling** | EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements |
| **User manual** | EN 1041:2008 +A1:2013 Information supplied by the manufacturer of medical devices |
| **General Requirements for Safety** | EN 60601-1:2006+A1:2013+A12:2014/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance<br>EN 60601-1-11:2015/ IEC 60601-1-11:2015 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 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests |
| **Performance requirements** | EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type |





| | |
|---|---|
| | IEC 80601-2-30:2018 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers |
| **Clinical investigation** | EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers<br>ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of intermittent automated measurement type |
| **Usability** | EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability<br>IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices |
| **Software life-cycle processes** | EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes |
| **Bio-compatibility** | ISO 10993-1:2018 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process<br>ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity<br>ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization |

# ♥ 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 TMB-2085, 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 excepted service life.
2. Guidance and manufacturer's declaration - electromagnetic emissions and Immunity





Table 1

| **Guidance and manufacturer's declaration - electromagnetic emissions** | |
|---|---|
| **Emissions test** | **Compliance** |
| RF emissions<br>CISPR 11 | Group 1 |
| RF emissions<br>CISPR 11 | Class B |
| Harmonic emissions<br>IEC 61000-3-2 | Not applicable |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Not applicable |

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<br>±2 kV, ±4kV, ±8 kV, ±15 kV air | ±8 kV contact<br>±2 kV, ±4kV, ±8 kV, ±15 kV air |
| Electrical fast transient/burst IEC 61000-4-4 | Not applicable | Not applicable |
| Surge IEC61000-4-5 | Not applicable | Not applicable |





| | | |
|---|---|---|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | Not applicable | Not applicable |
| Power frequency magnetic field IEC 61000-4-8 | 30 A/m<br>50Hz/60Hz | 30 A/m<br>50Hz/60Hz |
| Conduced RF IEC61000-4-6 | Not applicable | Not applicable |
| Radiated RF IEC61000-4-3 | 10 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 1 kHz | 10 V/m<br>80 MHz – 2,7 GHz<br>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 communications equipment) | Test Frequency (MHz) | Band (MHz) | Service | Modulation | Modulation (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
| | 385 | 380-390 | TETRA 400 | Pulse modulation b) 18Hz | 1.8 | 0.3 | 27 |
| | 450 | 430-470 | GMRS 460, FRS 460 | FM c) ± 5kHz deviation 1kHz sine | 2 | 0.3 | 28 |
| | 710 | 704-787 | LTE Band 13,17 | Pulse modulation b) 217Hz | 0.2 | 0.3 | 9 |
| | 745 | | | | | | |
| | 780 | | | | | | |
| | 810 | 800-960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation b) 18Hz | 2 | 0.3 | 28 |
| | 870 | | | | | | |
| | 930 | | | | | | |





| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1720 | 1700-1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS | Pulse modulation b) 217Hz | 2 | 0.3 | 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 |
| | 5240 | 5100-5800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| | 5500 | | | | | | |
| | 5785 | | | | | | |