



Guangdong Transtek Medical Electronics Co., Ltd.

广东乐心医疗电子股份有限公司

TRANSTEK

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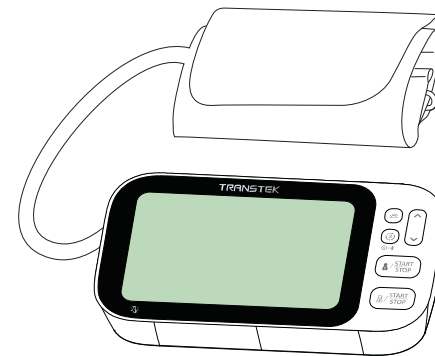
Version:A/0

TRANSTEK

User Manual

Blood Pressure Monitor Model: BBY36-BT

Arm Type



- Thank you very much for selecting TRANSTEK Blood Pressure Monitor BBY36-BT.
- Please do read the user manual carefully and thoroughly so as to ensure the safe usage of this product, and keep the manual well for further reference in case you have problems.


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♥ General Description

Thank you for selecting TRANSTEK blood pressure monitor (BBY36-BT). The monitor features blood pressure measurement, pulse rate measurement and the result storage.

Readings taken by theBBY36-BT are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step by step instructions for using the product.

Read the manual thoroughly before using the product.

Features:

- 124mm×76mm Digital LCD display with white backlight
- Maximum 250 records
- Drop measurement

♥ Indications for Use

This Blood Pressure Monitor is intended for use in measuring blood pressure and pulse rate in patients with arm circumferences from 22cm to 45cm (about 8¾"-17¼"), and is intended for adult population, including those with atrial fibrillation.

For 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 atmospheric pressure. Then it starts inflating the arm cuff. When inflated to a certain pressure, the arm cuff starts deflating. 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.

♥ Receiving and Inspecting your Monitor

Check that the device packaging has not been tampered with and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Services address.

♥ 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 |  | Serial Number |
|  | Date of manufacture |  | Manufacturer |
|  | Class II Equipment |  | For indoor use only |
|  | Batch code | | |
|  | Consult instructions for use or consult electronic instructions for use. | | |
|  | 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 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. | | |

INTRODUCTION

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 adults. Do not use this device on neonates or infants. Do not use it on children unless otherwise instructed by a medical professional.
- * Consult with your physician before using this monitor if you suffer from the following conditions: common arrhythmias such as premature ventricular beats; peripheral arterial disease; pregnancy; preeclampsia; 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.

Caution

- * **DO NOT** attempt to repair the unit yourself if it malfunctions. Only have repairs carried out by authorized 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.

INTRODUCTION

Warning

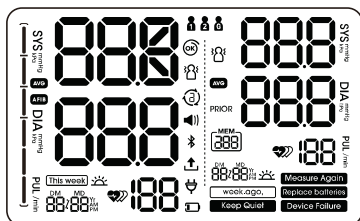
- * **DO NOT** self-diagnose the measurement results and start treatment by yourself. The measurement results given by this device is not a diagnosis. **ALWAYS** consult your doctor for evaluation of the results and treatment.
- * **DO NOT** adjust medication based on readings from this blood pressure 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.
- * 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.
- * 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.
- * **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.
- * 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.
- * Sensor degradation or looseness may reduce performance of device or cause other problems.

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.

INTRODUCTION

♥ LCD display signal

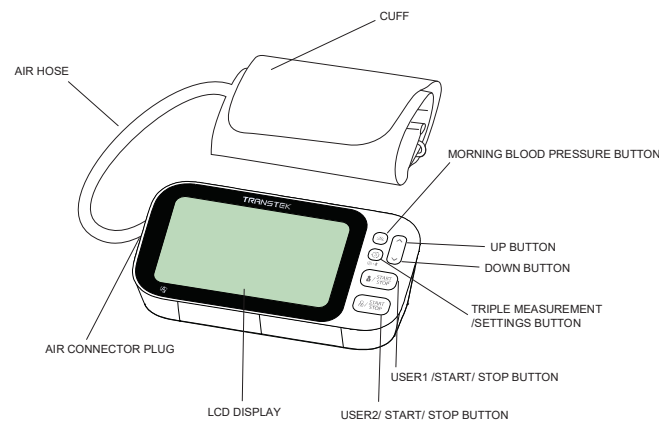


| SYMBOL | DESCRIPTION | EXPLANATION |
|-----------------------|--------------------------|--|
| SYS | Systolic blood pressure | High pressure result. |
| DIA | Diastolic blood pressure | Low pressure result. |
| PUL /min | Pulse display | Pulse in beats per minute. |
| mmHg | mmHg | Measurement unit of blood pressure. |
| kPa | kPa | Measurement unit of blood pressure. |
| 00:00 00:00 | Current Time | Time(year:month:day:hour:minute) |
| | Pulse rate | Pulse rate detection during measurement. |
| | Irregular pulse rate | Appears when detected during a measurement. Refer to page 29 for more information. |
| | Memory Query | Indicate it is in the memory mode and which group of memory it is. |
| | User ID | Appears when the monitor is operated by the selected user. |
| | Triple Mode | Three consecutive measurements with 1 minute interval in between. |
| | Average sign | The average of the last 3 measurements (within 30 minutes). |
| | Cuff wearing | The cuff is secured. |
| | Blood pressure level | Indicate blood pressure level. |
| | Battery Indicator | Indicate the current battery. |
| | Powered by adapter | Indicate that the adapter is currently powered. |
| | Hand shaking | Data is transmitting. |
| | Data transmitting | Measurement unit of blood pressure. |
| | Voice icon | Indicates volume level |

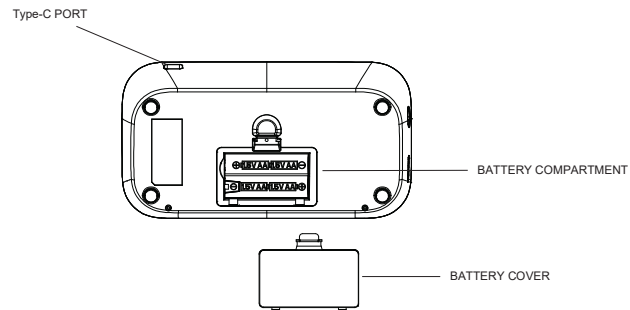
INTRODUCTION

| SYMBOL | DESCRIPTION | EXPLANATION |
|--------|--|--|
| | Atrial fibrillation symbol | Suspected atrial fibrillation alert. |
| | Bluetooth icon | Indicate the bluetooth is working |
| | This week's morning blood pressure | Indicate the average morning blood pressure result for this week. |
| | Morning blood pressure | Screen all the average results of morning blood pressure in memory. |
| | Last result | Indicate the last result. |
| | Morning blood pressure a few weeks ago | Indicated the average morning blood pressure result for a few weeks ago. |
| | Vivid tips | Keep quiet. |
| | Vivid tips | Remeasure. |
| | Vivid tips | Please replace the battery. |
| | Vivid tips | Device errors. |

♥ Monitor Components



INTRODUCTION



♥ List

1. Blood Pressure Monitor (BBY36-BT)

2. Cuff (Type BF applied part)
Upper arm cuff: 22~45cm



3. 4×AA batteries



4. TYPE-C USB cable



5. AC adapter (Optional)



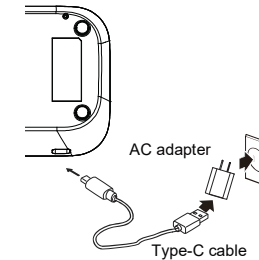
6. User manual

BEFORE YOU START

♥ Choice of Power Supply

1. Battery powered mode:
6V DC 4×AA batteries
2. AC adaptor powered mode:
5V \equiv 1A (Optional!)
(Please use the AC adapter which is authorized by the manufacturer!)

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

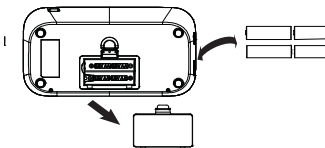


⚠ CAUTION


In order to get the best effect and protect your monitor, please use the right batteries 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 happen

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




⚠ CAUTION

- New and used batteries, or different types of batteries shall not be used together.
- Remove batteries if the device is not likely to be used for some time.
- Do not heat or deform the batteries, or dispose of them in fire.
- Batteries should not be disposed of with household waste.
- Please check with your local authority for battery recycling advice.

BEFORE YOU START

♥ Setting Voice, Date and Time

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of the year :2024—2054 time format: 12H/24H)

1. Install the battery for the first time or press and hold the “SETTING” button about 3 seconds to enter setting mode.(Voice broadcast: Please follow the voice instructions to complete the setup before measurement)
It will display the bluetooth symbol  first, then press the “SETTING” button to enter the [Voice] setting(Voice broadcast: Volume setting).
Press the  or  button to change the Voice volume(Voice broadcast: “volume 1”, “volume 2” or “mute”).







(Voice: volume 1)



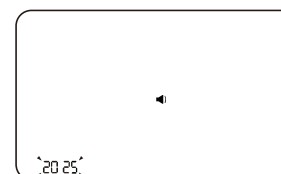
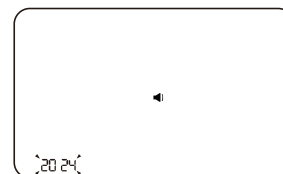
(Voice: volume 2)



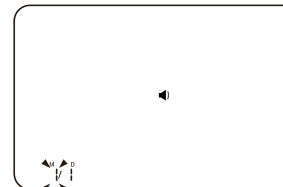
(Voice: mute)



2. Press the “SETTINGS” button to confirm the voice, then the [Year] will flash.
press the  or  button to change the year.
Press and hold the  button to quickly advance the years.
Press and hold the  button to quickly go backwards through the years.
(Voice broadcast: Year setting)

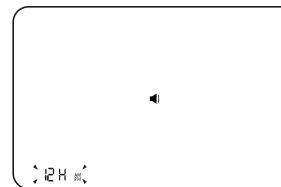
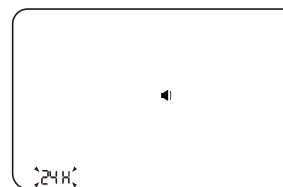
BEFORE YOU START



3. Press the “SETTINGS” button to confirm the year, then the [month] will flash.
Repeat the same steps to change the month, day.
(Voice broadcast: Date setting)

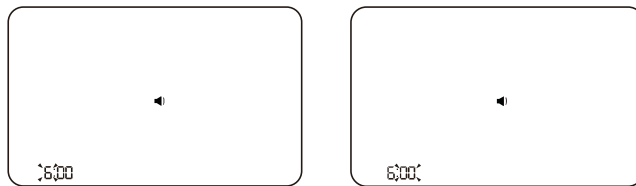


4. Press the “SETTINGS” button to confirm the date, then the [time format] will flash.
Press the  or  button to change the time format between [24H] and [12H].
(Voice broadcast: Time format setting)



BEFORE YOU START

- Press the "SETTINGS" button to confirm the time format, then the [hour] will flash.
Repeat the same steps to change hour and minute.
(Voice broadcast: Time setting)





- After confirming the [Minute], the LCD will display all the settings you have done, and then it will display "do nE" and the device will turn off automatically.
(Voice broadcast: End Settings)



♥ Pair a smart device with the monitor

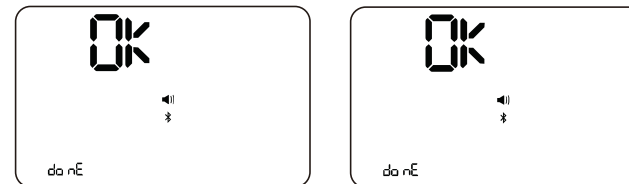
You are the intended operator of this blood pressure monitor. You can measure your blood pressure and then save and send measurement data to a smart device (such as smartphone or tablet) with Bluetooth wireless connectivity and application.

BEFORE YOU START

- Turn on the Bluetooth and the app on your smart device.
Make sure both are ON when pair-up is proceeding.
- When the monitor is off, press and hold the "SETTINGS" button to start pair-up, the bluetooth symbol  will flash.
(Voice broadcast : Please follow the voice instructions to complete the setup before measurement, pairing started, please wait)
- If successful**, the bluetooth symbol  will not flash any more the LCD will display "do nE", and enter the [Voice] setting. (Voice broadcast: Paired successfully)

Note

The date and time on your monitor will automatically be set after paired with your smart device successfully.



(Voice: Bluetooth pairing)

(Voice: Paired successfully)


If unsuccessful within 60 seconds, it is judged timeout and the monitor will shut off.

(Voice broadcast: Pairing failed)

Note

Press the SETTINGS button can skip Bluetooth pairing.

BEFORE YOU START

| Specifications for Bluetooth Transmission | | |
|---|-----------------------|--------------|
| Bluetooth | Throughput | 2.5K-5K |
| | Latency | 50ms |
| | PER | ≤5% |
| | Operating Frequency | 2402-2480MHz |
| | Transmission Power | 0±2dBm |
| | Transmission Distance | 10m |
| Note: 1. The necessary Quality of Service (QoS) is fully considered here for wirelessly enabled functions. 2. Interference may occur in the vicinity of equipment marked with the following symbol  . And BBY36-BT may interfere the vicinal electrical equipment. 3. Keep the monitor at least 20 centimeters away from the human body (especially the head) when data transmission is proceeding after measurement. 4. To enable the data transmission function, this device shall be paired to an appropriate BT mobile terminal. | | |

Warning

About a wireless communication interference

The monitor operates in the unlicensed ISM band at 2.4 GHz. In case it is used around the other wireless devices including microwave and wireless LAN, which operate at the same frequency band as the monitor, there is a possibility that interference occurs between the monitor and such other devices. If such interference occurs, please stop the operation of other devices or relocate the monitor before using it or do not use it around the other wireless devices.

List of compatible devices:

For iOS devices: The operating system must be iOS 13.0 or more.

For Android devices: The operating system must be Android 5.0 or more.

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** allow others to log into the APP, as it may lead to leakage of measurement data.
- * **DO NOT** casually use the APP account 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.
- * The password of the APP account should be set as possibly complicated and well kept, for the sake of account security.
- * Be aware of the environmental security while setting password.
- * It's recommended to update the password of the APP account at least once every 3 months.
- * **DO NOT** use the APPs that are not authorized by the manufacturer.

MEASUREMENT

♥ 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.

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 your palm facing up and tie the cuff on your upper arm, align the Artery indicator ϕ with the main Artery (on the inside of your arm).**

Note: Locate the main Artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest, that is your main Artery!

4. **Make sure the bottom edge of the arm cuff 2 to 3 cm 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.

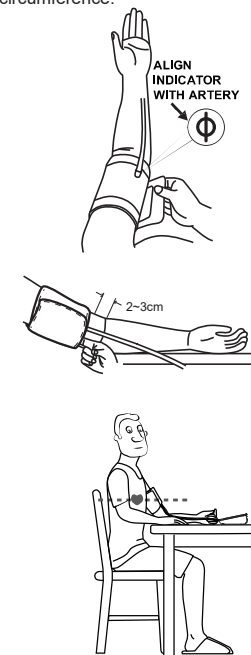
5. **Sit upright in a comfortable chair with your back against the backrest of the chair. Keep your feet flat and your legs uncrossed.**

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:

- Take the measurement in a silent room.
- Rest for 5 minutes before a measurement.
- Wait at least 3 minutes before another measurement. This allows your blood circulation to recover.
- Be relaxed and do not move and talk during the measurement procedure.
- 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.



MEASUREMENT


♥ Setting a user ID

There are 3 user ID    available. The user  and , each with 250 memory spaces, are designed for 2 different people to save the measured values separately. The user , no memory space, is reserved for guest.

This Blood Pressure Monitor is not designed with independent user buttons or toggle switches to select users, and uses a composite form of "USER + START/STOP".

When the monitor is OFF, press the "USER 1 + START/STOP" button, it will be measured by .

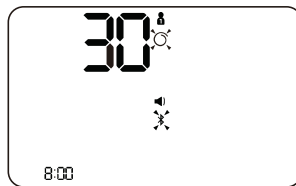
When the monitor is OFF, press the "USER 2 + START/STOP" button, it will be measured by .


When the monitor is OFF, press and hold the "USER 2 + START/STOP" button, it will be measured by . (Measurement data is not saved)

♥ Start the Measurement

A. Single measurement

1. When the monitor is OFF, press the "USER 1 + START/STOP" button, it will finish the whole measurement automatically, save and transmit the measurement data for the selected user. (Take User 1 for example.)



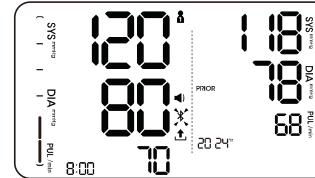
Adjust the zero.
Cuff wrap detection,
symbol "  " flash



Cuff wrap ok.
Inflating and measuring.

(Voice: User one, Starting measurement,
please remain still and quiet.)

MEASUREMENT



Display and save the
measurement.

(Voice: your systolic pressure is 120,
diastolic pressure is 80, Pulse is 70)

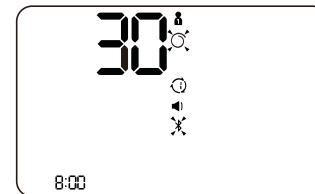


Measurement over range.

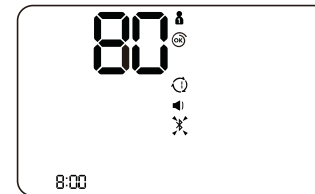
B. Atrial Fibrillation Screening (During the triple measurement)

1. When the monitor is OFF, press the "TRIPLE MEASURE" button, it will finish the whole measurement automatically, save and transmit the measurement data for the selected user. (Take User 1 for example.)

After the first and second measurements are completed, there will be no results. After all three measurement is completed, the average results of the three measurements will be displayed.



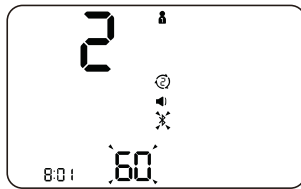
Cuff wrap detection



Cuff wrap ok.
Inflating and measuring

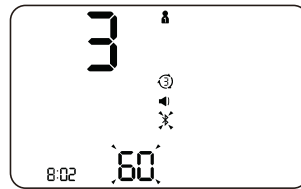
(Voice: User one, Starting triple measurement,
please remain still and quiet.)

MEASUREMENT



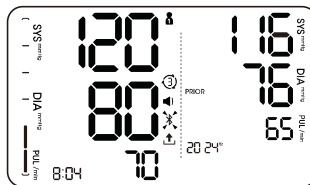
The second measurement
(60 seconds
countdown display)

(Voice: Please keep quiet and
do not move.)



The third measurement
(60 seconds
countdown display)

(Voice: Please keep quiet and
do not move.)



Display and save
the measurement result

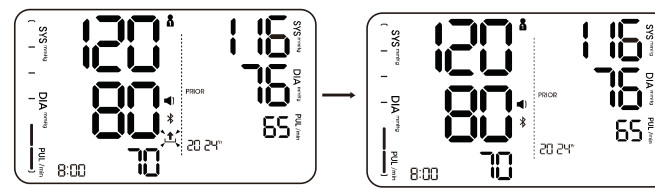
(Voice: Your systolic pressure is 120, diastolic pressure is 80, pulse is 70.)

2. After the measurement was finished, the bluetooth symbol “” blinks and data transmission starts. (Please connect the app during the transmission)

If data transmission successful, the symbol “” will not blink and “” will disappear, and then the monitor will turn off automatically after about 1 minute.

If unsuccessful within 60 seconds, it is judged timeout and the monitor will shut off.

MEASUREMENT



3. Press “START/ STOP” button to turn off, otherwise it will turn off automatically.

Note

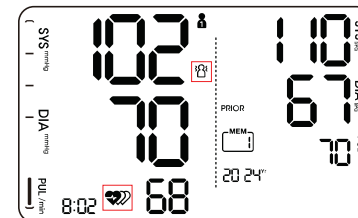
Any time if you want to stop the measurement, you can press and hold the “START/ STOP” button or wait for 30 seconds, and the measurement will be saved.

4. About the irregular pulse rate and excessive body motion during the measurement.

- During a measurement, If an irregular pulse rate is detected, the symbol will display in the measurement result. See page 29 for more information.
- During the measurement, if atrial fibrillation is detected, the atrial fibrillation symbol will be displayed.
- During a measurement, when the excessive body motion, especially of the arm the cuff is worn is detected, the symbol will flash about 5 seconds and detect again. If it is no longer detected, the symbol will disappear; If still detected, the symbol will final display in the measurement result.

Note

The measured blood pressure reading may not be accurate if this symbol is displayed.

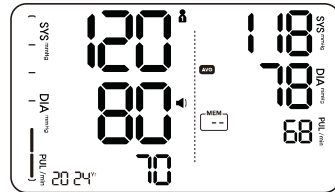


♥ Recall the Records

When the monitor is off, press the “UP” or “DOWN” button to enter user memory mode.

Press the “UP” or “DOWN” button to change the user between USER 1 and USER 2. Press the “SETTINGS” button to confirm the selection. If the user does not press the “SETTINGS” button to confirm, confirmation will be confirmed automatically after 3 seconds.

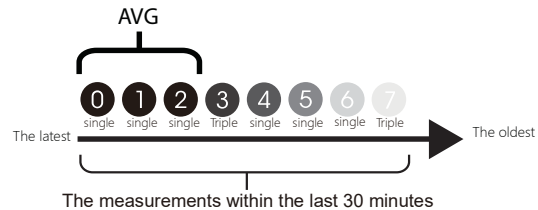
1. When the monitor is off, press the  button, it displays the average of the three measurements within the last 30 minutes, with the average symbol. (Take User 1 for example.)




(Voice: User 1, Last measurement, your systolic pressure is 120, diastolic pressure is 80, pulse is 70 and average your systolic pressure is 118, diastolic pressure is 78, pulse is 68)

Note

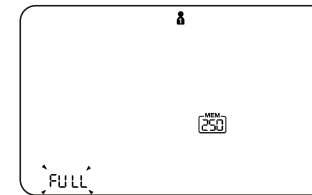
- If there are not enough 3 records within 30 minutes, after entering the memory mode, the most recent measurement record will be directly displayed.



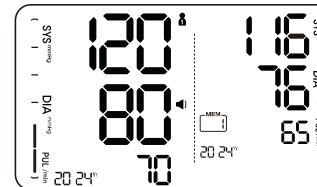
2. When the monitor is off, press the  button, it displays the oldest record. (Voice broadcast : Memory XXX, Your systolic pressure is XXX, diastolic pressure is XXX, pluse is XX)

Note

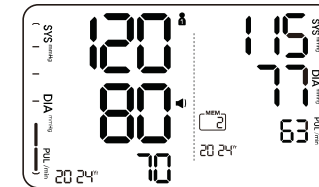
- Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (250) is dropped from the list.



3. Press the  or  button to display the next record.

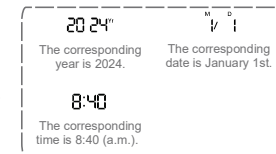


The current record
is Group 1.



The current record
is Group 2.

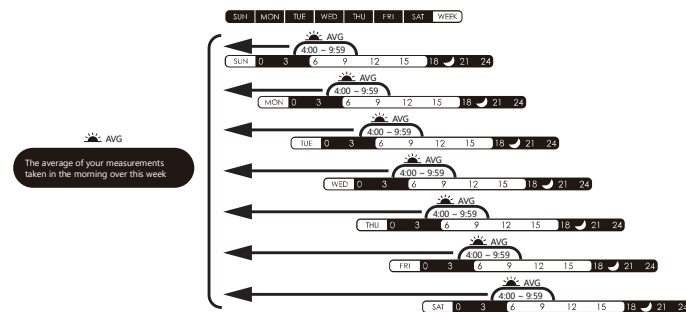
Date, Time and Year
will display alternately.



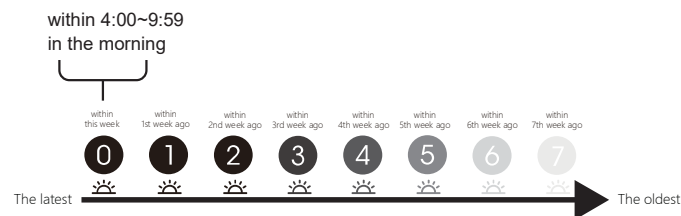
♥ Morning Blood Pressure

Average of 7 days combined, starting on Sunday of this week and ending on Saturday of this week.

The time period for taking the value: within 4:00~9:59 in the morning of the same day.



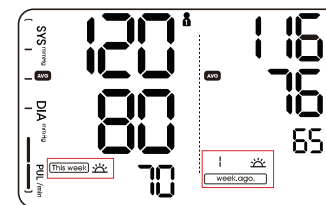
“This week” Indicates the average morning blood pressure for the week. The records on the right are the average morning blood pressure from 7th week ago to 1st week ago.



1. When the monitor is off, press the ☀ button to enter user memory mode.

Press the “UP” or “DOWN” button to change the user between USER 1 and USER 2. Press the “SETTINGS” button to confirm the selection. If the user does not press the “SETTINGS” button to confirm, confirmation will be confirmed automatically after 3 seconds.

2. Press the ^ button, the number of memory mode increases (1st week ago → 2nd week ago → ...)
Press the v button, the number of memory mode increases (1st week ago → the oldest → ...)








(Voice: User one, The average of your measurements taken in the morning over this week, your systolic pressure is 120, diastolic pressure is 80, Pulse is 70; The average of your measurements taken in the morning 1 week ago, your systolic pressure is 116, diastolic pressure is 76, Pulse is 65.

♥ Delete the Records

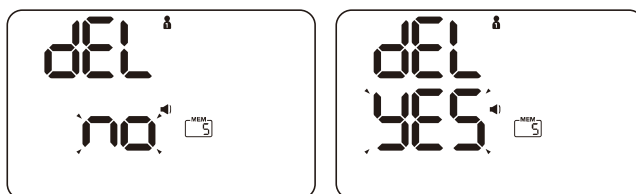
If you did not get the correct measurement, you can delete results by following steps below.

A: To delete a single measurement:

1. Enter the memory recall mode as described in section [Recall the Records]. Press the  or  button to get the measurement you would like to erase.
2. Press and hold  button for about 3 seconds, and the display will show a blinking "dEL no".
3. Use the  or  button to switch between "dEL yES" and "dEL no", Press "SETTINGS" button to confirm the selection.

If "dEL yES" is selected, the unit will delete the record and will display "do nE" + User ID, after then it will return to last memory record and all the records are pushed forward one digit (e.g., 03 becomes 02, and so on).
If "dEL no" is selected, it will stop the deletion.

(Voice broadcast: Delete current data)






"dEL no" blinks
(Voice: Canceled)

"dEL yES" blinks
(Voice: Deleted)



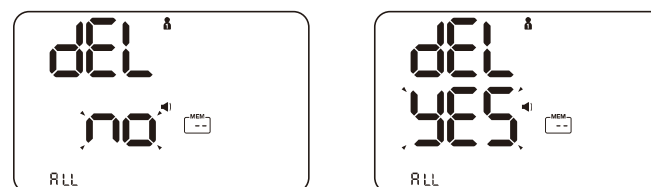
Deletion is done

B: To delete all measurements:

1. Enter the memory recall mode as described in section [Recall the Records].
2. Press and hold  and "USER 1+START/STOP" button button for 3 seconds, and the display will show a blinking "dEL no" along with the user ID.
3. Use the  or  button to switch between "dEL yES" and "dEL no", Press "SETTINGS" button to confirm the selection.

If "dEL ALL" is selected, the unit will display "do nE" + User ID, and delete all the record of the current user. Several seconds later, it will display "—".
If "dEL no" is selected, it will stop the deletion.

(Voice broadcast: Delete all data)

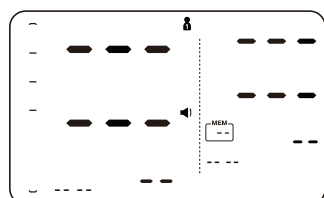


"dEL no" blinks
(Voice: Canceled)

"dEL yES" blinks
(Voice: Deleted)



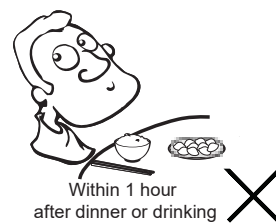
Deletion is done



No record

♥ 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



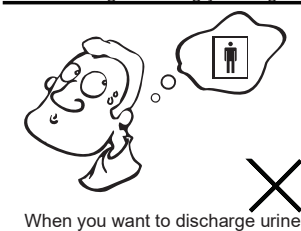
Within 20 minutes
after taking a bath



When talking or moving your fingers



In a very cold environment



When you want to discharge urine

♥ Maintenance

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:

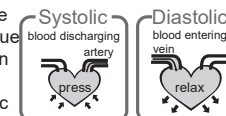
Frequency of Cleaning and Disinfection:

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.

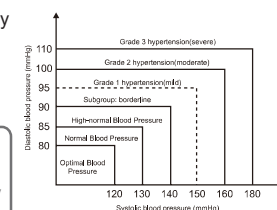
♥ What are systolic pressure and diastolic pressure?

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

| Level Blood Pressure (mm Hg) | Optimal | Normal | High-normal | Mild | Moderate | Severe |
|---------------------------------|---------|---------|-------------|---------|----------|--------|
| SYS | <120 | 120-129 | 130-139 | 140-159 | 160-179 | ≥180 |
| DIA | <80 | 80-84 | 85-89 | 90-99 | 100-109 | ≥110 |

♥ Irregular Pulse Rate Detector

An irregular pulse rate will be detected if there is an irregular pulse rhythm while measuring systolic and diastolic blood pressure. When measurements were performed, the monitor will record all pulse intervals and calculate the average. If two or more pulse intervals were recorded, and the difference between each interval and the average is larger than $\pm 25\%$ of the average; or if four or more pulse intervals were recorded, and the difference between each interval and the average is larger than $\pm 15\%$ of the average value, the irregular pulse symbol will be displayed along with measurement results.

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?

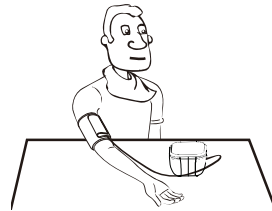
The blood pressure is different even throughout the day due to weather, emotion, exercise etc. Also, there is the "white coat" effect, which means blood pressure usually increases in clinical settings.

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 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.



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

| PROBLEM | SYMPTOM | CHECK THIS | REMEDY |
|-----------------|--|---|---|
| No power | Display can not light up. | Batteries are depleted. | Replace with new batteries. |
| | | Batteries are inserted incorrectly. | Insert the batteries correctly. |
| High Battery | bAt H shows | The battery is too high. | Replace with the correct DC plug. |
| Low Battery | bAt Lo &  shows | The battery is too low. | Replace with new batteries. |
| Error message | E 01 shows | The cuff is not wrapped or wrapped incorrectly, or the cuff air plug is loose. | Refasten the cuff and insert air tube plug correctly then measure again. |
| | E 02 or  shows | Excessive body motion (such as shaking of the arm with the cuff on) or weak Pulse is detected. | Relax for 5 minutes. and then keep still, measure again. |
| | E 03 shows | Pulse is not detected during measuring. | Loosen the clothing on the arm and measure again. |
| | E04+EEx shows | Device failure. (X can be some digital symbol, such as 01, 02, etc., if this similar situation appear, all belong to device failure.) | 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 and then measure again. If the problem persists, contact your physician. |

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

SPECIFICATIONS

| | |
|---|--|
| Power supply | Battery powered mode: 6V DC 4×AA batteries AC adaptor powered mode: 5V \pm 1A (Optional!) (Please only use the recommended AC adaptor model). |
| Display mode | Digital LCD V.A. 124 × 76 mm |
| Measurement mode | Oscillographic testing mode |
| Measurement range | Rated cuff pressure: 0mmHg~299mmHg Measurement pressure: SYS: 60mmHg~260mmHg (8.0kPa~34.7kPa) DIA: 40mmHg~215mmHg (5.3kPa~28.7kPa) Pulse value: (40-199)beat/minute |
| Accuracy | Static Pressure: 5 °C~40 °C within \pm 3mmHg Pulse value: \pm 5% Clinical validation: Mean difference within \pm 5mmHg; Standard deviation \leq 8mmHg |
| Normal working condition | A temperature range of: +5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but notrequiring 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 \leq 93%, non-condensing, at a water vapour pressure up to 50 hPa An atmospheric pressure range of 500 hPa to 1060 hPa |
| Measurement perimeter of the upper arm | About 22~45cm |
| Weight | Approx.390g (Excluding the batteries and cuff) |
| External dimensions | Approx.191.4 × 103.4 × 59.8 mm |
| Attachment | 4×AA batteries, Type-C USB cable, 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 be protected against solid foreign objects of 12.5mm Φ and greater, and against vertically falling water drops. |
| Device Classification | Battery Powered Mode: Internally Powered ME Equipment |
| Software Version | A01 |
| Expected Lifetime | Device: 5 years or 30,000 measurements (may vary based on usage conditions) Cuff: 10000 times Alkaline battery: About 200-300 times AC adapter: 35000 hours |
| Types of use/reuse | Multiple patient multiple use |

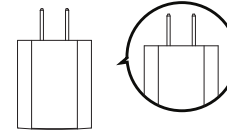
32

WARNING: No modification of this equipment is allowed.

AUTHORIZED COMPONENT

♥ Authorized Component

Please use the TRANSTEK authorized adapter. (Optional!)



Adapter

Model: HNEM050100UU

Input: 100-240V, 50-60Hz, 0.2A max

Output: 5V \pm 1A

♥ 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

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♥ EMC Guidance

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

Essential performance:

Accuracy of measuring blood pressure and pulse rate

| | |
|----------------------------|---|
| Measurement Range | Systolic pressure: 60~260 mmHg Diastolic pressure: 40~215 mmHg Pulse: 40~199 beats/minute |
| Rated Cuff Pressure | 0~299 mmHg (0~39.9 kPa) |
| Accuracy | Pressure: ± 3 mmHg / 0.4 kPa |
| Laboratory reproducibility | ≤ 3 mmHg |

The Basis Safety of the Blood Pressure Monitor (BBY36-BT) is as following:
Deviation from normal operation that poses an unacceptable risk to the patient or operator.

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 |
| 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 |
| Conducted 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 communications 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 | | | | | | | |

FCC STATEMENT

♥ FCC Statement

FCC ID: OU9BBY36-BT

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 a minimum distance of 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: KCH, 575 Lexington Ave 14F New York, NY 10022

Telephone: 301-910-0529

E-mail: mio@transtekcorp.com